

US3222388 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:03:07

All time stamps listed in this document are displayed in GMT

US3222388

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

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[Participant ID](#)

US3222388

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

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US3222388

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3222388

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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

US3222388

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3222388

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3222388

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

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Were any significant conditions reported?

Yes ☒

No ☐

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US3222388

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

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



US3222388

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Condition	HYPERTENSION
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)	_____

US3222388

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Condition	NEUROPATHY WITH FEET
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)	

US3222388

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222388

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Condition	ADVANCED MULTILEVEL DEGENERATIVE CHANGES SPONDYLOSIS OF THE LUMBAR SPINE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222388

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:06
Height (xxx.x)	180.3 cm
Weight (xxx.x)	84.0 kg
BMI (xxx.x)	25.83972 kg/m <sup>2</sup>
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)	

US3222388

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3222388

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 17:05:23

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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 ☒

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**Specify**

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False



US3222388

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 145177

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 ☒

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Height	ND - Not Done
Weight	ND - Not Done

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:09
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:28
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)	80 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3222388

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 15:58 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 15:58

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



US3222388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	15:25 (24 HR)
Collection date and time (derived)	28 AUG 2020 15:25

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:28	28 AUG 2020 15:28
Nasopharyngeal Swab 2	No		

US3222388

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:23

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 AUG 2020 16:34

PC Open Date & Time

28 AUG 2020 16:18

PC Close Date & Time

28 AUG 2020 18:48

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	28 AUG 2020 20:41
PC Open Date & Time	28 AUG 2020 19:43
PC Close Date & Time	29 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:38

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 13:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

02 SEP 2020 13:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 16:35

PC Open Date & Time

28 AUG 2020 16:18

PC Close Date & Time

28 AUG 2020 18:48

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:42

PC Open Date & Time

28 AUG 2020 19:43

PC Close Date & Time

29 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:38

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:05

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 13:07

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:35
PC Open Date & Time	28 AUG 2020 16:18
PC Close Date & Time	28 AUG 2020 18:48

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:43
PC Open Date & Time	28 AUG 2020 19:43
PC Close Date & Time	29 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:39
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2174

EAB) (1725)

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2174

EAB) (1725)

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 13:05
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2174

EAB) (1725)



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:07
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 2174

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 15:49
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3222388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222388

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

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

Visit date (dd MMM yyyy)	17 OCT 2020
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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	VISIT2
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US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 OCT 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	17 OCT 2020 11:28
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 OCT 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	17 OCT 2020 12:35
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3222388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 OCT 2020

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

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:56 (24 HR)

Treatment Date and Time (derived) 17 OCT 2020 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

US3222388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 OCT 2020

Collection time (00:00-23:59)

11:48 (24 HR)

Collection date and time (derived)

17 OCT 2020 11:48

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Collection date (dd MMM yyyy)			17 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:54	17 OCT 2020 11:54
Nasopharyngeal Swab 2	No		



US3222388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 12:32

PC Open Date & Time

17 OCT 2020 12:16

PC Close Date & Time

17 OCT 2020 14:46

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	17 OCT 2020 17:06
PC Open Date & Time	17 OCT 2020 15:41
PC Close Date & Time	18 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 13:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

19 OCT 2020 16:43

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

20 OCT 2020 12:09

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 19:28

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

22 OCT 2020 15:42

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 12:33

PC Open Date & Time

17 OCT 2020 12:16

PC Close Date & Time

17 OCT 2020 14:46

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 17:06

PC Open Date & Time

17 OCT 2020 15:41

PC Close Date & Time

18 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 13:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 16:44

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 12:09

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 19:28

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 15:42

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

PC Time stamp	17 OCT 2020 12:33
PC Open Date & Time	17 OCT 2020 12:16
PC Close Date & Time	17 OCT 2020 14:46

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

PC Time stamp	17 OCT 2020 17:07
PC Open Date & Time	17 OCT 2020 15:41
PC Close Date & Time	18 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 16:44
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2174

EAB) (1725)

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 12:09
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2174

EAB) (1725)

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 19:28
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 15:43
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

103 of 2174



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 12:03
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3222388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:04:52

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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



US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3222388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

11:19 (24 HR)

Collection date and time (derived)

11 NOV 2020 11:19

US3222388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:24

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 00:02:18
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 03:09:02

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59



US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 NOV 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 16:35:00
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 14:44:40

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 00:15:27
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 138

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 152

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 159

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 FEB 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 13:05:42

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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



US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 09:25:56

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 13:01:19
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 00:40:01
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 03:34:10

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 18:57:25

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 22:47:17

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2021 23:59



US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 13:21:30
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 243

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 250

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 285

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 327

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUL 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 348

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 369

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 376

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 418

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 425

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 453

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 467

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 495

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JAN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 516

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 530

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 537

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 544

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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 ☐



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAR 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 586

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 628

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 642

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 649

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 677

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 698

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 719

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 754

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59
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US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

DAY 782

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

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

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

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

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3222388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:03:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 09:25:24

US3222388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:05:22

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO GET IN CONTACT  
WITH SUBJECT. VOICEMAIL  
NOT SET UP.

*If Contact Not Made, please provide Comments*

US3222388

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3222388**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:03:07**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3222388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3222388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3222388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

**US3222388**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:03:07**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222388

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:03:07

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>



**US3222388**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:03:07**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3222388

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3222388

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

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

US3222388

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3222388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00 - 23:59</i> )	<hr/>
Collection Date and Time (derived)	<hr/>

US3222388

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

AEID	USA-US104-2020-MRNA-1273-P30 1000009
Adverse event	LUMBAR CANAL AND FORAMINA STENOSIS
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	334 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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ADVANCED MULTILEVEL  
DEGENERATIVE CHANGES AND  
SPONDYLOSIS OF THE LUMBAR  
SPINE WITH MULTILEVEL  
FORAMINAL STENOSIS.

1. STATUS POST POSTERIOR  
DECOMPRESSION AT L3-S1
2. LUMBAR SPINE NO ACUTE  
FRACTURE
3. NO FOCAL ALIGNMENT  
ABNORMALITIES
4. NEURAL FORAMINA L4-5  
MODERATE BILATERAL  
FORAMINAL STENOSIS FROM  
ADJACENT SEVERE LOSS OF  
DISC HEIGHT, POSTERIOR  
SPONDYLOSIS AND FACET  
ARTHROPATHY
5. SPINAL CANAL, POSTERIOR  
SPONDYLOSIS, LIGAMENTUM  
FLAVUM HYPERTROPHY AND  
FACET ARTHROPATHY LIKELY  
CONTRIBUTING TO L1-2 MILD  
CANAL STENOSIS, AND L2-3  
MILD TO MODERATE CANAL  
STENOSIS.
6. NO ACUTE FRACTURE IN THE  
LUMBAR SPINE
7. CANAL STENOSIS AND  
FORAMINAL STENOSIS

---

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

---

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

AEID	USA-US104-2020-MRNA-1273-P30 1000009
Adverse event	LUMBAR PAIN AT SURGERY SITE.
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)	8 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	9 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	337 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

---

SUBJECT NOTIFIED ME TODAY  
@ 13:33 THAT HE IS BACK IN  
THE HOSPITAL FOR LOWER  
BACK PAIN AT THE SURGICAL  
SITE. HE ARRIVED YESTERDAY  
AND MAY BE RELEASED  
TOMORROW AND WILL CALL  
ME WHEN HE IS DISCHARGED.

---

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

---

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

AEID

Adverse event

UNCONTROLLED  
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

340 of 2174

EAB) (1725)

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

AEID

Adverse event

ABDOMINAL PAIN (COLONIC  
DIVERTICULA)

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)

1 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

342 of 2174

EAB) (1725)

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	



US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

---

WITHOUT EVIDENCE OF  
DIVERTICULITIS.  
THIS WAS DISCOVERED BY CT  
OF THE ABDOMEN AND PELVIS  
W/C.  
THIS WAS DISCOVERED BY CT  
OF THE ABDOMEN AND PELVIS  
W/C.  
NOT TREATED AFTER  
DISCOVERY.

---

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)	

---

---

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

345 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☐  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal ☐  
Not Recovered/Not Resolved ☒  
Recovered/Resolved ☐  
Recovered/Resolved with Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative THIS WAS DISCOVERED BY CT  
OF THE ABDOMEN AND PELVIS  
W/C.  
THIS WAS DISCOVERED BY CT  
OF THE ABDOMEN AND PELVIS  
W/C.  
NOT TREATED AFTER  
DISCOVERY.

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed:** (b) (4) 26 Apr 2021 14:30:01

**Generated On: 09 Jun 2021 16:03:07**

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)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

348 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☐  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal ☐  
Not Recovered/Not Resolved ☒  
Recovered/Resolved ☐  
Recovered/Resolved with ☐  
Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative THIS WAS DISCOVERED BY CT  
OF THE ABDOMEN AND PELVIS  
W/C.  
NOT TREATED AFTER  
DISCOVERY.

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)

PRODUCTION RELEASE (v12.003

349 of 2174

EAB) (1725)

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:30:01

Generated On: 09 Jun 2021 16:03:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. NOT TREATED AFTER DISCOVERY.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
PRODUCTION RELEASE (v12.003 EAB) (1725)	
351 of 2174	



**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Data signed:** (b) (4) 26 Apr 2021 14:30:01

**Generated On: 09 Jun 2021 16:03:07**

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Admitted to ICU Derived (CSA Programming Field Only)

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US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

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

Yes ☒

No ☐

---

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

---

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY TO FEET

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

356 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication ATENOLOL

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

360 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication OXYCODONE/APAP

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR CANAL AND  
FORAMINA STENOSIS

Dose per administration 10/325

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication AMLODIPINE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

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



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR CANAL AND  
FORAMINA STENOSIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

1 TABLET 3 TIMES A DAY FOR 2  
DAYS. 1 TABLET TWICE A DAY  
FOR 2 DAYS. 1 TABLET DAILY  
FOR 2 DAYS.

Route of administration Oral ☒  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication DIAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR CANAL AND  
FORAMINA STENOSIS

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

TID/PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

370 of 2174

EAB) (1725)

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication DICYCLOMINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLELITHIASIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication FENTANYL PATCH

Prophylaxis Yes ☐  
No ☒

Indication S/P LAMINECTOMY  
PAIN MANAGEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 3 DAYS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

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



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:30:02

Generated On: 09 Jun 2021 16:03:07

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

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 17:04:51

Generated On: 09 Jun 2021 16:03:07

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 SEP 2020	LAMINECTOMY	Adverse Event	
14 SEP 2020	CT ABD AND PELVIS W/C	Diagnostic	
14 SEP 2020	CT L SPINE W/O CONTRAST	Diagnostic	

US3222388

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:03:07

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3222388

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	09/OCT/2020 19:01
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



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	06/NOV/2020 17:55
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

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:48
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

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 10:39
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

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	30/MAR/2021 12:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 14:30:03

Generated On: 09 Jun 2021 16:03:07

SAEID	USA-US104-2020-MRNA-1273-P301000009
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)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 13:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3222388 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222388

Form: Participant Creation

Generated On: 09 Jun 2021 16:03:07

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'US3222388'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:10:08

US3222388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:49



US3222388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:10:09

US3222388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Clinic (Clinic)'	Crystal Paccione (b) (4)	28 Aug 2020 20:31:49

US3222388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'SCRN'	System	28 Aug 2020 20:31:49

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:10:10

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '59'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'YEARS'	System	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '59'	System	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Aug 2020 15:44:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 15:44:29
User entered 'Male (M)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	29 Aug 2020 15:44:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Aug 2020 15:44:22
User entered empty.	System	29 Aug 2020 15:44:22
	Amber Vasquez (b) (4)	29 Aug 2020 15:44:22
	(b) (4)	



US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'I'	Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4)	
	Amber Vasquez (b) (4)	29 Aug 2020 15:44:22
	(b) (4)	



US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:44:22

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'Aug 2020'	System	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '2020'	System	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Amendment 3 (3)'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:31:59



US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:31:59

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:10:09

US3222388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'I'	System	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:03:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:03:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:18

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:39:00
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'DIET CONTROLLED' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:03:52
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 21:57:43
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:46:40
Data point term sent to Coder	System	29 Aug 2020 15:45:40
User entered 'Diabetes Type II'	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'un UNK 2016'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:35



US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'Jan 2016'	System	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '2016'	System	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:45:35

US3222388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:45:35



US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Per CDM: Response noted however, please confirm date of related concomitant medication and provide update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 12:11:02
Query 'Per CDM: Response noted however, please confirm date of related concomitant medication and provide update.' answered with 'DIAGNOSED IN 2005, BEGAN TREATMENT IN 2015.' (Site from DM).	douglas winter (b) (4) (b) (4)	05 Nov 2020 17:09:14
User opened query 'Per CDM: Response noted however, please confirm date of related concomitant medication and provide update.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 17:42:16
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.		19 Oct 2020 17:42:16
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:41
' answered with 'UPDATED CONMED PAGES' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	10 Sep 2020 21:59:12
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:47:40

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Aug 2020 15:47:40
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	29 Aug 2020 15:46:43
User entered 'Hypertension'	Amber Vasquez (b) (4)	29 Aug 2020 15:45:58
	(b) (4)	

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'un UNK 2005'	Amber Vasquez (b) (4)	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'Jan 2005'	System	29 Aug 2020 15:45:58



US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '2005'	System	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:45:58

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 09:53:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 09:53:41
User closed query 'Per CDM: Please provide location (arm, legs,). Please review and update medical history diagnosis as appropriate and ensure update to Medical History is reconciled with corresponding concomitant medication or adverse event, if applicable.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 21:15:20
Data point term sent to Coder	System	05 Nov 2020 17:11:20
Query 'Per CDM: Please provide location (arm, legs,). Please review and update medical history diagnosis as appropriate and ensure update to Medical History is reconciled with corresponding concomitant medication or adverse event, if applicable.' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4)	05 Nov 2020 17:10:49
Coding entries removed.	douglas winter (b) (4)	05 Nov 2020 17:10:39
User entered 'NEUROPATHY WITH FEET' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 17:10:39
User opened query 'Per CDM: Please provide location (arm, legs,). Please review and update medical history diagnosis as appropriate and ensure update to Medical History is reconciled with corresponding concomitant medication or adverse event, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 17:48:40
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 17:48:40

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED CONMED PAGES' (Site from DM).	douglas winter (b) (4)	09 Oct 2020 17:12:54
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	10 Sep 2020 21:59:48
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Aug 2020 15:47:40
Data point term sent to Coder	System	29 Aug 2020 15:46:43
User entered 'Neuropathy'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:26
	(b) (4)	

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'un UNK 2005'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:46:26



US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Amber Vasquez (b) (4)	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'Jan 2005'	System	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '2005'	System	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:46:26

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:48:41
Data point term sent to Coder	System	29 Aug 2020 15:47:44
User entered 'GERD'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'un UNK 2015'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:46



US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'Jan 2015'	System	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '2015'	System	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:46:46

US3222388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Aug 2020 15:46:46



US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per MM, please split and record each condition separately as applicable' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 11:45:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Lumbar spondylosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:12:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:12:30
Query 'Per MM, please split and record each condition separately as applicable' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:33:49
Data point term sent to Coder	System	29 Mar 2021 16:33:43
User closed query 'CDM coding: Please split the reported term ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAINAL STENOSIS to capture coding for all the conditions reported. Example: 1) ADVANCED MULTILEVEL DEGENERATIVE CHANGES SPONDYLOSIS OF THE LUMBAR SPINE 2) MULTILEVEL FORAMINAL LUMBAR STENOSIS' (Site from System).	System	29 Mar 2021 16:33:34
Query 'CDM coding: Please split the reported term ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAINAL STENOSIS to capture coding for all the conditions reported. Example: 1) ADVANCED MULTILEVEL DEGENERATIVE CHANGES SPONDYLOSIS OF THE LUMBAR SPINE 2) MULTILEVEL FORAMINAL LUMBAR STENOSIS' answered with 'updated' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 16:33:34
User entered 'ADVANCED MULTILEVEL DEGENERATIVE CHANGES SPONDYLOSIS OF THE LUMBAR SPINE' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 16:33:17

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per MM, please split and record each condition separately as applicable' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:15:15
User opened query 'CDM coding: Please split the reported term ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAINAL STENOSIS to capture coding for all the conditions reported. Example: 1) ADVANCED MULTILEVEL DEGENERATIVE CHANGES SPONDYLOSIS OF THE LUMBAR SPINE 2) MULTILEVEL FORAMINAL LUMBAR STENOSIS' (Site from System).	Coder Import (b) (4)	17 Mar 2021 08:44:42
Data point term sent to Coder	System	06 Mar 2021 18:29:29
User entered 'ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAINAL STENOSIS.'	douglas winter (b) (4)	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	06 Mar 2021 18:29:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	douglas winter (b) (4)	06 Mar 2021 18:29:25
User entered ' UN' (non-conformant).	(b) (4)	
	System	06 Mar 2021 18:29:02
	douglas winter (b) (4)	06 Mar 2021 18:29:02
	(b) (4)	

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	06 Mar 2021 18:29:02



US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	06 Mar 2021 18:29:02

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Vertebral foraminal stenosis, LLT: Lumbar foraminal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 13:04:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 13:04:33
Data point term sent to Coder	System	29 Mar 2021 16:35:45
User entered 'MULTILEVEL FORAMINAL LUMBAR STENOSIS'	(b) (4), (b) (6)	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:34:48



US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered empty.	System	29 Mar 2021 16:34:48

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '15:06'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11



US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '28 Aug 2020 15:06'	System	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '180.3' cm	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '84.0' kg	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered '25.83972'	System	29 Aug 2020 15:48:11
DataPoint set to visible.	System	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'kg/m2'	System	29 Aug 2020 15:48:11
DataPoint set to visible.	System	28 Aug 2020 20:32:04

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
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)	13 Oct 2020 21:49:15
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)	25 Sep 2020 12:13:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	25 Sep 2020 12:13:01
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 16:59:45
User entered '36.7' C	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	25 Sep 2020 12:13:01
	(b) (4)	
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:11
	(b) (4)	

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:11



US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:01
User entered '86'	Albert Garcia (b) (4)	29 Aug 2020 15:48:11
	(b) (4)	

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'bpm'	System	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:01
User entered '16'	Albert Garcia (b) (4)	29 Aug 2020 15:48:11
	(b) (4)	

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'breaths/min'	System	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:01
User entered '138'	Albert Garcia (b) (4)	29 Aug 2020 15:48:11
	(b) (4)	

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'mmHg'	System	29 Aug 2020 15:48:11

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:01
User entered '88'	Albert Garcia (b) (4)	29 Aug 2020 15:48:11
	(b) (4)	

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User entered 'mmHg'	System	29 Aug 2020 15:48:11



US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14

US3222388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14

US3222388

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:24

US3222388

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:24

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57



US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57



US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57

US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '0'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:48:57



US3222388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4)	
	Amber Vasquez (b) (4)	29 Aug 2020 15:48:57
	(b) (4)	

US3222388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:16

US3222388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:32:16

US3222388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:16

US3222388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'VISIT1'	System	28 Aug 2020 20:32:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:24:32

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '145177'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:24:32

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:24:32



US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:49:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Amber Vasquez (b) (4)	29 Aug 2020 15:49:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:49:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:49:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:49:16

US3222388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Albert Garcia (b) (4)	25 Sep 2020 12:13:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:32:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:32:29

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '183.0' cm	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '84.0' kg	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56



US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '183.0' cm	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '84.0' kg	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '15:09'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '28 Aug 2020 15:09'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '36.7' C	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56



US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '86'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'bpm'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '16'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'breaths/min'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '148'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	29 Aug 2020 15:51:56



US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '87'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '183.0' cm	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 12:13:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	02 Sep 2020 16:05:03
User entered '84.0' kg	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Sep 2020 16:05:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Sep 2020 16:05:35
User entered '15:28' reason for change: Data Entry Error	Amber Vasquez (b) (4)	02 Sep 2020 16:05:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 15:51:56
User entered empty.	System	29 Aug 2020 15:51:56
	Amber Vasquez (b) (4)	29 Aug 2020 15:51:56
	(b) (4)	



US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '28 Aug 2020 15:28'	System	02 Sep 2020 16:05:35
User entered empty.	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '36.7' C	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '80'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'bpm'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '16'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'breaths/min'	System	29 Aug 2020 15:51:56



US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '140'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '88'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	29 Aug 2020 15:51:56

US3222388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:52:13

US3222388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:52:13

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:47



US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4)	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '15:58'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'ONCE'	System	28 Aug 2020 20:32:47

US3222388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 20:32:47



US3222388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:52:54

US3222388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:52:54

US3222388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '15:25'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:52:54

US3222388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '28 Aug 2020 15:25'	System	29 Aug 2020 15:52:54

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '28 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '15:28'	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:53:09



US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '28 Aug 2020 15:28'	System	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	29 Aug 2020 15:53:09

US3222388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Per CDM: Visit 2 forms not completed. Please complete.' (Site from DM).	(b) (4)	11 Nov 2020 15:15:22
Query 'Per CDM: Visit 2 forms not completed. Please complete.' answered with 'UPDATED VISIT 2' (Site from DM).	douglas winter (b) (4)	05 Nov 2020 19:09:29
User opened query 'Per CDM: Visit 2 forms not completed. Please complete.' (Site from DM).	(b) (4)	14 Oct 2020 14:48:27
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	29 Aug 2020 15:53:16

US3222388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'I'	System	29 Aug 2020 15:53:16

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd282e746-90b5-4256-be9b-ad78f30dbcba'	System	28 Aug 2020 20:34:35
User entered 'Yes (Y)'	System	28 Aug 2020 20:34:35

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd282e746-90b5-4256-be9b-ad78f30dbcba'	System	28 Aug 2020 20:34:35
User entered '98.1'	System	28 Aug 2020 20:34:35

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd282e746-90b5-4256-be9b-ad78f30dbcba'	System	28 Aug 2020 20:34:35
User entered 'No (N)'	System	28 Aug 2020 20:34:35

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:34', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd282e746-90b5-4256-be9b-ad78f30dbcba'	System	28 Aug 2020 20:34:35
User entered '28 Aug 2020 16:34'	System	28 Aug 2020 20:34:35

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 16:18'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 18:48'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:41:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1874731-97cc-487d-b250-24e1767ae568'	System	29 Aug 2020 00:41:44
User entered 'Yes (Y)'	System	29 Aug 2020 00:41:44



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:41:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1874731-97cc-487d-b250-24e1767ae568'	System	29 Aug 2020 00:41:44
User entered '98.1'	System	29 Aug 2020 00:41:44

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:41:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1874731-97cc-487d-b250-24e1767ae568'	System	29 Aug 2020 00:41:44
User entered 'No (N)'	System	29 Aug 2020 00:41:44

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:41:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1874731-97cc-487d-b250-24e1767ae568'	System	29 Aug 2020 00:41:44
User entered '28 Aug 2020 20:41'	System	29 Aug 2020 00:41:44

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 19:43'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 2'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:37:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '40878783-1538-4dfc-8967-74c8036b48b5'	System	29 Aug 2020 16:38:22
User entered 'Yes (Y)'	System	29 Aug 2020 16:38:22

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:04', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '40878783-1538-4dfc-8967-74c8036b48b5'	System	29 Aug 2020 16:38:22
User entered '98.2'	System	29 Aug 2020 16:38:22



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '40878783-1538-4dfc-8967-74c8036b48b5'	System	29 Aug 2020 16:38:22
User entered 'No (N)'	System	29 Aug 2020 16:38:22

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:20', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '40878783-1538-4dfc-8967-74c8036b48b5'	System	29 Aug 2020 16:38:22
User entered '29 Aug 2020 12:38'	System	29 Aug 2020 16:38:22

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 3'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'ab3c3e5a-afe5-4ef2-bc4a-637ded9f4ad0'	System	30 Aug 2020 16:02:26
User entered 'Yes (Y)'	System	30 Aug 2020 16:02:26

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:01:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'ab3c3e5a-afe5-4ef2-bc4a-637ded9f4ad0'	System	30 Aug 2020 16:02:26
User entered '98.1'	System	30 Aug 2020 16:02:26

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:01:48', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'ab3c3e5a-afe5-4ef2-bc4a-637ded9f4ad0'	System	30 Aug 2020 16:02:26
User entered 'No (N)'	System	30 Aug 2020 16:02:26



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:01:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'ab3c3e5a-afe5-4ef2-bc4a-637ded9f4ad0'	System	30 Aug 2020 16:02:26
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:02:26

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 4'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:04:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1737c2a-c6a9-4426-bca0-2e4afb877ae2'	System	31 Aug 2020 16:08:55
User entered 'Yes (Y)'	System	31 Aug 2020 16:08:55

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:04:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1737c2a-c6a9-4426-bca0-2e4afb877ae2'	System	31 Aug 2020 16:08:55
User entered '98.1'	System	31 Aug 2020 16:08:55

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:04:43', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1737c2a-c6a9-4426-bca0-2e4afb877ae2'	System	31 Aug 2020 16:08:55
User entered 'No (N)'	System	31 Aug 2020 16:08:55

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:04:48', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b1737c2a-c6a9-4426-bca0-2e4afb877ae2'	System	31 Aug 2020 16:08:55
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:08:55



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 5'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:03:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '515ecf07-78de-426f-8907-eaed03e28b3a'	System	01 Sep 2020 17:03:57
User entered 'Yes (Y)'	System	01 Sep 2020 17:03:57

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:03:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '515ecf07-78de-426f-8907-eaed03e28b3a' User entered '98.3'	System	01 Sep 2020 17:03:57
	System	01 Sep 2020 17:03:57

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:03:52', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '515ecf07-78de-426f-8907-eaed03e28b3a'	System	01 Sep 2020 17:03:57
User entered 'No (N)'	System	01 Sep 2020 17:03:57

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:03:58', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '515ecf07-78de-426f-8907-eaed03e28b3a'	System	01 Sep 2020 17:03:57
User entered '01 Sep 2020 13:03'	System	01 Sep 2020 17:03:57

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 6'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '170dd029-52f7-4a77-a76a-e20094c1e661'	System	02 Sep 2020 17:06:37
User entered 'Yes (Y)'	System	02 Sep 2020 17:06:37

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '170dd029-52f7-4a77-a76a-e20094c1e661'	System	02 Sep 2020 17:06:37
User entered '98.3'	System	02 Sep 2020 17:06:37

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:32', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '170dd029-52f7-4a77-a76a-e20094c1e661'	System	02 Sep 2020 17:06:37
User entered 'No (N)'	System	02 Sep 2020 17:06:37

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:35', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '170dd029-52f7-4a77-a76a-e20094c1e661'	System	02 Sep 2020 17:06:37
User entered '02 Sep 2020 13:06'	System	02 Sep 2020 17:06:37

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 7'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:47:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1cf9d757-f472-4742-8b78-de2966a4d613'	System	03 Sep 2020 19:48:15
User entered 'Yes (Y)'	System	03 Sep 2020 19:48:15

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:06', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1cf9d757-f472-4742-8b78-de2966a4d613'	System	03 Sep 2020 19:48:15
User entered '98.1'	System	03 Sep 2020 19:48:15

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1cf9d757-f472-4742-8b78-de2966a4d613'	System	03 Sep 2020 19:48:15
User entered 'No (N)'	System	03 Sep 2020 19:48:15

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:15', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1cf9d757-f472-4742-8b78-de2966a4d613'	System	03 Sep 2020 19:48:15
User entered '03 Sep 2020 15:48'	System	03 Sep 2020 19:48:15

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '094ed5fd-a158-4ff6-9e3a-20f747b315ce'	System	28 Aug 2020 20:35:13
User entered 'None (1)'	System	28 Aug 2020 20:35:13

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '094ed5fd-a158-4ff6-9e3a-20f747b315ce'	System	28 Aug 2020 20:35:13
User entered 'No (N)'	System	28 Aug 2020 20:35:13

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:34:58', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '094ed5fd-a158-4ff6-9e3a-20f747b315ce'	System	28 Aug 2020 20:35:13
User entered 'No (N)'	System	28 Aug 2020 20:35:13

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:04', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '094ed5fd-a158-4ff6-9e3a-20f747b315ce'	System	28 Aug 2020 20:35:13
User entered 'None (1)'	System	28 Aug 2020 20:35:13

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '094ed5fd-a158-4ff6-9e3a-20f747b315ce'	System	28 Aug 2020 20:35:13
User entered '28 Aug 2020 16:35'	System	28 Aug 2020 20:35:13

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 16:18'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 18:48'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:05', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '3baa9f68-4b0b-41ff-9e16-c0fdd60b2155'	System	29 Aug 2020 00:42:32
User entered 'None (1)'	System	29 Aug 2020 00:42:32

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '3baa9f68-4b0b-41ff-9e16-c0fdd60b2155'	System	29 Aug 2020 00:42:32
User entered 'No (N)'	System	29 Aug 2020 00:42:32

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:16', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '3baa9f68-4b0b-41ff-9e16-c0fdd60b2155'	System	29 Aug 2020 00:42:32
User entered 'No (N)'	System	29 Aug 2020 00:42:32

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:22', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '3baa9f68-4b0b-41ff-9e16-c0fdd60b2155'	System	29 Aug 2020 00:42:32
User entered 'None (1)'	System	29 Aug 2020 00:42:32

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '3baa9f68-4b0b-41ff-9e16-c0fdd60b2155'	System	29 Aug 2020 00:42:32
User entered '28 Aug 2020 20:42'	System	29 Aug 2020 00:42:32

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 19:43'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 2'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '95a77f68-9db8-4c0b-bbaf-bbc532f3b6cc'	System	29 Aug 2020 16:38:54
User entered 'None (1)'	System	29 Aug 2020 16:38:54

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:34', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '95a77f68-9db8-4c0b-bbaf-bbc532f3b6cc'	System	29 Aug 2020 16:38:54
User entered 'No (N)'	System	29 Aug 2020 16:38:54

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:40', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '95a77f68-9db8-4c0b-bbaf-bbc532f3b6cc'	System	29 Aug 2020 16:38:54
User entered 'No (N)'	System	29 Aug 2020 16:38:54

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:46', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '95a77f68-9db8-4c0b-bbaf-bbc532f3b6cc'	System	29 Aug 2020 16:38:54
User entered 'None (1)'	System	29 Aug 2020 16:38:54

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:38:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '95a77f68-9db8-4c0b-bbaf-bbc532f3b6cc'	System	29 Aug 2020 16:38:54
User entered '29 Aug 2020 12:38'	System	29 Aug 2020 16:38:54

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 3'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:04', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e5e2b637-7667-48c2-9eeb-baf215c5042d'	System	30 Aug 2020 16:03:01
User entered 'None (1)'	System	30 Aug 2020 16:03:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:08', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e5e2b637-7667-48c2-9eeb-baf215c5042d'	System	30 Aug 2020 16:03:01
User entered 'No (N)'	System	30 Aug 2020 16:03:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e5e2b637-7667-48c2-9eeb-baf215c5042d'	System	30 Aug 2020 16:03:01
User entered 'No (N)'	System	30 Aug 2020 16:03:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e5e2b637-7667-48c2-9eeb-baf215c5042d'	System	30 Aug 2020 16:03:01
User entered 'None (1)'	System	30 Aug 2020 16:03:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:31', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e5e2b637-7667-48c2-9eeb-baf215c5042d'	System	30 Aug 2020 16:03:01
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 16:03:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 4'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:04:57', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7d2eb763-9608-4301-8942-f81597272ffc'	System	31 Aug 2020 16:09:08
User entered 'None (1)'	System	31 Aug 2020 16:09:08

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7d2eb763-9608-4301-8942-f81597272ffc'	System	31 Aug 2020 16:09:08
User entered 'No (N)'	System	31 Aug 2020 16:09:08

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:06', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7d2eb763-9608-4301-8942-f81597272ffc'	System	31 Aug 2020 16:09:08
User entered 'No (N)'	System	31 Aug 2020 16:09:08

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7d2eb763-9608-4301-8942-f81597272ffc'	System	31 Aug 2020 16:09:08
User entered 'None (1)'	System	31 Aug 2020 16:09:08

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:14', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7d2eb763-9608-4301-8942-f81597272ffc'	System	31 Aug 2020 16:09:08
User entered '31 Aug 2020 12:05'	System	31 Aug 2020 16:09:08

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 5'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:09', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cb6bcda8-6097-4d21-a854-8e87579d9ea7'	System	01 Sep 2020 17:04:29
User entered 'None (1)'	System	01 Sep 2020 17:04:29

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cb6bcda8-6097-4d21-a854-8e87579d9ea7'	System	01 Sep 2020 17:04:29
User entered 'No (N)'	System	01 Sep 2020 17:04:29

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cb6bcda8-6097-4d21-a854-8e87579d9ea7'	System	01 Sep 2020 17:04:29
User entered 'No (N)'	System	01 Sep 2020 17:04:29

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:23', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cb6bcda8-6097-4d21-a854-8e87579d9ea7'	System	01 Sep 2020 17:04:29
User entered 'None (1)'	System	01 Sep 2020 17:04:29

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cb6bcda8-6097-4d21-a854-8e87579d9ea7'	System	01 Sep 2020 17:04:29
User entered '01 Sep 2020 13:04'	System	01 Sep 2020 17:04:29

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 6'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4e89007-0adb-4f91-9acc-0e46aac6be55'	System	02 Sep 2020 17:07:01
User entered 'None (1)'	System	02 Sep 2020 17:07:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4e89007-0adb-4f91-9acc-0e46aac6be55'	System	02 Sep 2020 17:07:01
User entered 'No (N)'	System	02 Sep 2020 17:07:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:51', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4e89007-0adb-4f91-9acc-0e46aac6be55'	System	02 Sep 2020 17:07:01
User entered 'No (N)'	System	02 Sep 2020 17:07:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:06:55', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4e89007-0adb-4f91-9acc-0e46aac6be55'	System	02 Sep 2020 17:07:01
User entered 'None (1)'	System	02 Sep 2020 17:07:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:01', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4e89007-0adb-4f91-9acc-0e46aac6be55'	System	02 Sep 2020 17:07:01
User entered '02 Sep 2020 13:07'	System	02 Sep 2020 17:07:01

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 7'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:21', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bbb45c9c-150a-4119-9898-fa3dcdf888d4'	System	03 Sep 2020 19:48:38
User entered 'None (1)'	System	03 Sep 2020 19:48:38

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:25', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bbb45c9c-150a-4119-9898-fa3dcdf888d4'	System	03 Sep 2020 19:48:38
User entered 'No (N)'	System	03 Sep 2020 19:48:38

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bbb45c9c-150a-4119-9898-fa3dcdf888d4'	System	03 Sep 2020 19:48:38
User entered 'No (N)'	System	03 Sep 2020 19:48:38

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bbb45c9c-150a-4119-9898-fa3dcdf888d4'	System	03 Sep 2020 19:48:38
User entered 'None (1)'	System	03 Sep 2020 19:48:38

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bbb45c9c-150a-4119-9898-fa3dcdf888d4'	System	03 Sep 2020 19:48:38
User entered '03 Sep 2020 15:48'	System	03 Sep 2020 19:48:38

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:34', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:39', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:44', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'None (0)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:52', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered 'No (N)'	System	28 Aug 2020 20:36:01

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T16:35:58', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e9feca9b-c881-442b-93ef-27d42af1d378'	System	28 Aug 2020 20:36:01
User entered '28 Aug 2020 16:35'	System	28 Aug 2020 20:36:01



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 16:18'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 18:48'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:43:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:42:58', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:43:02', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:43:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'None (0)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:43:12', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered 'No (N)'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-28T20:43:32', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bd8ba1c1-865f-4282-a87a-c64ead1c7f18'	System	29 Aug 2020 00:43:33
User entered '28 Aug 2020 20:43'	System	29 Aug 2020 00:43:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '28 Aug 2020 19:43'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 2'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:02', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:06', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:15', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:22', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'None (0)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered 'No (N)'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-29T12:39:31', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2a6c7dad-d95e-4a39-b6c1-04973bc65868'	System	29 Aug 2020 16:39:33
User entered '29 Aug 2020 12:39'	System	29 Aug 2020 16:39:33

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 3'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c'	System	30 Aug 2020 16:03:37
User entered 'None (0)'	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c'	System	30 Aug 2020 16:03:37
User entered 'None (0)'	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c'	System	30 Aug 2020 16:03:37
User entered 'None (0)'	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:48', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c' User entered 'None (0)'	System	30 Aug 2020 16:03:37
	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c' User entered 'None (0)'	System	30 Aug 2020 16:03:37
	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:02:56', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c' User entered 'None (0)'	System	30 Aug 2020 16:03:37
	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:03:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c'	System	30 Aug 2020 16:03:37
User entered 'No (N)'	System	30 Aug 2020 16:03:37



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-30T12:03:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a8b41109-5e9b-4ba0-a85d-03648716472c'	System	30 Aug 2020 16:03:37
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 16:03:37

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 4'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:21', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:39', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'None (0)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:46', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered 'No (N)'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-08-31T12:05:50', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a27dc6de-6575-43e9-bf13-9eba02052d49'	System	31 Aug 2020 16:09:24
User entered '31 Aug 2020 12:05'	System	31 Aug 2020 16:09:24

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 5'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:35', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:39', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:46', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:04:57', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'None (0)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:05:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered 'No (N)'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-01T13:05:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6be5cd95-b727-4162-94ea-980900d45c90'	System	01 Sep 2020 17:05:10
User entered '01 Sep 2020 13:05'	System	01 Sep 2020 17:05:10

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:32:47



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 6'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:17', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:20', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:30', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'None (0)'	System	02 Sep 2020 17:07:43



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered 'No (N)'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-02T13:07:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '41ef5bbe-1b3e-4595-9917-044d5f0efe8c'	System	02 Sep 2020 17:07:43
User entered '02 Sep 2020 13:07'	System	02 Sep 2020 17:07:43

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 7'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:44', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:50', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15



US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:48:57', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:49:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'None (0)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:49:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered 'No (N)'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-09-03T15:49:14', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '50d4d750-8eec-4d96-8d97-24a37bb989a5'	System	03 Sep 2020 19:49:15
User entered '03 Sep 2020 15:49'	System	03 Sep 2020 19:49:15

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:32:47

US3222388

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:25



US3222388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 16:26:21
User entered '4 Sep 2020'	(b) (4)	
	Crystal Paccione (b) (4)	17 Oct 2020 16:27:25
	(b) (4)	

US3222388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	17 Oct 2020 16:27:25

US3222388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:25

US3222388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	17 Oct 2020 16:27:30

US3222388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	17 Oct 2020 16:27:30

US3222388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:44

US3222388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '11 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:44

US3222388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:44



US3222388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered empty.	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:44

US3222388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:27:49

US3222388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	17 Oct 2020 16:27:49

US3222388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:01

US3222388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '18 Sep 2020'	Crystal Paccione (b) (4)	17 Oct 2020 16:28:01

US3222388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:01

US3222388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered empty.	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:01

US3222388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:06



US3222388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	17 Oct 2020 16:28:06

US3222388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Per CDM: Please complete remaining Visit 2 forms.' (Site from DM).	(b) (4)	24 Nov 2020 14:38:40
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17OCT2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17OCT2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED DATA' (Site from DM).	douglas winter (b) (4)	05 Nov 2020 17:30:48
Query 'Per CDM: Please complete remaining Visit 2 forms.' answered with 'COMPLETED REST OF THE VISIT' (Site from DM).	(b) (4)	05 Nov 2020 17:30:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17OCT2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:55:42
User opened query 'Per CDM: Please complete remaining Visit 2 forms.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:31:49
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	17 Oct 2020 16:28:19

US3222388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:14:02
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'noted' (Site from System).	Crystal Paccione (b) (4) (b) (4)	17 Oct 2020 16:28:30
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Oct 2020 16:28:19
User entered '17 Oct 2020'	Crystal Paccione (b) (4) (b) (4)	17 Oct 2020 16:28:19

US3222388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	17 Oct 2020 16:28:19

US3222388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'VISIT2'	System	17 Oct 2020 16:28:19

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Pre-Dose (PREDOSE)'	douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18



US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11:28'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '17 Oct 2020 11:28'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '37.1' C	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Oral (Oral)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '95'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'bpm'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '19'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18



US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'breaths/min'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '129'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '81'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Post-Dose (POSTDOSE)'	douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 17:28:18
	(b) (4)	

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18



US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '12:35'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '17 Oct 2020 12:35'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '37.3' C	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Oral (Oral)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '90'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'bpm'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '18'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18



US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'breaths/min'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '114'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '78'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'mmHg'	System	05 Nov 2020 17:28:18

US3222388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:35

US3222388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:28:35

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:56



US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Crystal Paccione (b) (4)	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'MRNA-1273 OR PLACEBO'	System	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	Crystal Paccione (b) (4)	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11:56'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '17 Oct 2020 11:56'	System	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Right Arm (RIGHT ARM)'	Crystal Paccione (b) (4)	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'ONCE'	System	17 Oct 2020 16:28:56



US3222388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'INTRAMUSCULAR'	System	17 Oct 2020 16:28:56

US3222388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 17:29:07
	(b) (4)	

US3222388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:07

US3222388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11:48'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:07

US3222388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '17 Oct 2020 11:48'	System	05 Nov 2020 17:29:07

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '17 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37



US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11:54'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '17 Oct 2020 11:54'	System	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 17:29:37

**US3222388**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	05 Nov 2020 17:29:37

US3222388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	17 Oct 2020 16:29:04

US3222388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'I'	System	17 Oct 2020 16:29:04



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b7b31cb9-2d48-4e1f-9e2b-913115acf73c'	System	17 Oct 2020 16:32:37
User entered 'Yes (Y)'	System	17 Oct 2020 16:32:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b7b31cb9-2d48-4e1f-9e2b-913115acf73c'	System	17 Oct 2020 16:32:37
User entered '99.2'	System	17 Oct 2020 16:32:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:31', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b7b31cb9-2d48-4e1f-9e2b-913115acf73c'	System	17 Oct 2020 16:32:37
User entered 'No (N)'	System	17 Oct 2020 16:32:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b7b31cb9-2d48-4e1f-9e2b-913115acf73c'	System	17 Oct 2020 16:32:37
User entered '17 Oct 2020 12:32'	System	17 Oct 2020 16:32:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 12:16'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 14:46'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, after vaccination (at home)'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:05', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cf4cc141-c938-457c-9230-94eb4f902a9b'	System	17 Oct 2020 21:06:10
User entered 'Yes (Y)'	System	17 Oct 2020 21:06:10

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:05:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cf4cc141-c938-457c-9230-94eb4f902a9b'	System	17 Oct 2020 21:06:10
User entered '98.5'	System	17 Oct 2020 21:06:10

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:05:49', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cf4cc141-c938-457c-9230-94eb4f902a9b'	System	17 Oct 2020 21:06:10
User entered 'No (N)'	System	17 Oct 2020 21:06:10

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:09', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'cf4cc141-c938-457c-9230-94eb4f902a9b'	System	17 Oct 2020 21:06:10
User entered '17 Oct 2020 17:06'	System	17 Oct 2020 21:06:10

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 2'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:57:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'df2fa1ee-1e80-41e2-bd9d-7c8dab6e33b4'	System	18 Oct 2020 17:58:07
User entered 'Yes (Y)'	System	18 Oct 2020 17:58:07



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:57:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'df2fa1ee-1e80-41e2-bd9d-7c8dab6e33b4'	System	18 Oct 2020 17:58:07
User entered '98.7'	System	18 Oct 2020 17:58:07

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:57:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'df2fa1ee-1e80-41e2-bd9d-7c8dab6e33b4'	System	18 Oct 2020 17:58:07
User entered 'No (N)'	System	18 Oct 2020 17:58:07

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:05', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'df2fa1ee-1e80-41e2-bd9d-7c8dab6e33b4'	System	18 Oct 2020 17:58:07
User entered '18 Oct 2020 13:58'	System	18 Oct 2020 17:58:07

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 3'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1ac4d78e-1d03-4290-87c5-c0fdbccaf11a'	System	19 Oct 2020 20:43:42
User entered 'Yes (Y)'	System	19 Oct 2020 20:43:42

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:34', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1ac4d78e-1d03-4290-87c5-c0fdbccaf11a'	System	19 Oct 2020 20:43:42
User entered '98.4'	System	19 Oct 2020 20:43:42



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:39', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1ac4d78e-1d03-4290-87c5-c0fdbccaf11a'	System	19 Oct 2020 20:43:42
User entered 'No (N)'	System	19 Oct 2020 20:43:42

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:44', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '1ac4d78e-1d03-4290-87c5-c0fdbccaf11a'	System	19 Oct 2020 20:43:42
User entered '19 Oct 2020 16:43'	System	19 Oct 2020 20:43:42

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 4'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:08:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6c5c7c9a-1e2f-4efb-b7bc-fb5113100764'	System	20 Oct 2020 16:09:04
User entered 'Yes (Y)'	System	20 Oct 2020 16:09:04

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:08:55', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6c5c7c9a-1e2f-4efb-b7bc-fb5113100764'	System	20 Oct 2020 16:09:04
User entered '98.3'	System	20 Oct 2020 16:09:04

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6c5c7c9a-1e2f-4efb-b7bc-fb5113100764'	System	20 Oct 2020 16:09:04
User entered 'No (N)'	System	20 Oct 2020 16:09:04



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '6c5c7c9a-1e2f-4efb-b7bc-fb5113100764'	System	20 Oct 2020 16:09:04
User entered '20 Oct 2020 12:09'	System	20 Oct 2020 16:09:04

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 5'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:27:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '02b2f3b3-ca82-4ffb-b565-85ba7b277b65'	System	21 Oct 2020 23:28:01
User entered 'Yes (Y)'	System	21 Oct 2020 23:28:01

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:27:54', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '02b2f3b3-ca82-4ffb-b565-85ba7b277b65'	System	21 Oct 2020 23:28:01
User entered '98.3'	System	21 Oct 2020 23:28:01

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:27:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '02b2f3b3-ca82-4ffb-b565-85ba7b277b65'	System	21 Oct 2020 23:28:01
User entered 'No (N)'	System	21 Oct 2020 23:28:01

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '02b2f3b3-ca82-4ffb-b565-85ba7b277b65'	System	21 Oct 2020 23:28:01
User entered '21 Oct 2020 19:28'	System	21 Oct 2020 23:28:01



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 6'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '39c72d7c-6218-4556-bf8d-7dc3f1c14bb0'	System	22 Oct 2020 19:42:37
User entered 'Yes (Y)'	System	22 Oct 2020 19:42:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '39c72d7c-6218-4556-bf8d-7dc3f1c14bb0'	System	22 Oct 2020 19:42:37
User entered '97.9'	System	22 Oct 2020 19:42:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '39c72d7c-6218-4556-bf8d-7dc3f1c14bb0'	System	22 Oct 2020 19:42:37
User entered 'No (N)'	System	22 Oct 2020 19:42:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '39c72d7c-6218-4556-bf8d-7dc3f1c14bb0'	System	22 Oct 2020 19:42:37
User entered '22 Oct 2020 15:42'	System	22 Oct 2020 19:42:37

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 12:00'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 7'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:02:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'c3f955f5-e96b-4a45-a479-d639ae7aaaaf'	System	23 Oct 2020 16:04:53
User entered 'Yes (Y)'	System	23 Oct 2020 16:04:53

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:02:55', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'c3f955f5-e96b-4a45-a479-d639ae7aaaaf'	System	23 Oct 2020 16:04:53
User entered '98.2'	System	23 Oct 2020 16:04:53

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:02:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'c3f955f5-e96b-4a45-a479-d639ae7aaaaf'	System	23 Oct 2020 16:04:53
User entered 'No (N)'	System	23 Oct 2020 16:04:53

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:02', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'c3f955f5-e96b-4a45-a479-d639ae7aaaaf'	System	23 Oct 2020 16:04:53
User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:04:53

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '24 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:44', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '63d1b8c5-f0ca-4a73-a71c-75a0634d7847'	System	17 Oct 2020 16:33:03
User entered 'None (1)'	System	17 Oct 2020 16:33:03

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:49', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '63d1b8c5-f0ca-4a73-a71c-75a0634d7847'	System	17 Oct 2020 16:33:03
User entered 'No (N)'	System	17 Oct 2020 16:33:03

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '63d1b8c5-f0ca-4a73-a71c-75a0634d7847'	System	17 Oct 2020 16:33:03
User entered 'No (N)'	System	17 Oct 2020 16:33:03

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:32:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '63d1b8c5-f0ca-4a73-a71c-75a0634d7847'	System	17 Oct 2020 16:33:03
User entered 'None (1)'	System	17 Oct 2020 16:33:03

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '63d1b8c5-f0ca-4a73-a71c-75a0634d7847'	System	17 Oct 2020 16:33:03
User entered '17 Oct 2020 12:33'	System	17 Oct 2020 16:33:03

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 12:16'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 14:46'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, after vaccination (at home)'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:15', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd2deb609-6b98-4d4c-b29e-e8ddeba9be05'	System	17 Oct 2020 21:06:32
User entered 'None (1)'	System	17 Oct 2020 21:06:32

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd2deb609-6b98-4d4c-b29e-e8ddeba9be05'	System	17 Oct 2020 21:06:32
User entered 'No (N)'	System	17 Oct 2020 21:06:32

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd2deb609-6b98-4d4c-b29e-e8ddeba9be05'	System	17 Oct 2020 21:06:32
User entered 'No (N)'	System	17 Oct 2020 21:06:32

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd2deb609-6b98-4d4c-b29e-e8ddeba9be05'	System	17 Oct 2020 21:06:32
User entered 'None (1)'	System	17 Oct 2020 21:06:32

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd2deb609-6b98-4d4c-b29e-e8ddeba9be05'	System	17 Oct 2020 21:06:32
User entered '17 Oct 2020 17:06'	System	17 Oct 2020 21:06:32

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 2'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:14', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '87582da2-1272-4fd1-a6aa-15fc9d30b033'	System	18 Oct 2020 17:58:35
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 17:58:35

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '87582da2-1272-4fd1-a6aa-15fc9d30b033'	System	18 Oct 2020 17:58:35
User entered 'No (N)'	System	18 Oct 2020 17:58:35

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '87582da2-1272-4fd1-a6aa-15fc9d30b033'	System	18 Oct 2020 17:58:35
User entered 'No (N)'	System	18 Oct 2020 17:58:35

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '87582da2-1272-4fd1-a6aa-15fc9d30b033'	System	18 Oct 2020 17:58:35
User entered 'None (1)'	System	18 Oct 2020 17:58:35

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '87582da2-1272-4fd1-a6aa-15fc9d30b033'	System	18 Oct 2020 17:58:35
User entered '18 Oct 2020 13:58'	System	18 Oct 2020 17:58:35

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 3'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:49', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '58242eba-1694-40b0-b00e-8de484f72244'	System	19 Oct 2020 20:44:06
User entered 'None (1)'	System	19 Oct 2020 20:44:06

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '58242eba-1694-40b0-b00e-8de484f72244'	System	19 Oct 2020 20:44:06
User entered 'No (N)'	System	19 Oct 2020 20:44:06

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:43:57', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '58242eba-1694-40b0-b00e-8de484f72244'	System	19 Oct 2020 20:44:06
User entered 'No (N)'	System	19 Oct 2020 20:44:06

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:01', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '58242eba-1694-40b0-b00e-8de484f72244'	System	19 Oct 2020 20:44:06
User entered 'None (1)'	System	19 Oct 2020 20:44:06

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:05', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '58242eba-1694-40b0-b00e-8de484f72244'	System	19 Oct 2020 20:44:06
User entered '19 Oct 2020 16:44'	System	19 Oct 2020 20:44:06

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 4'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:08', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f2ee02f9-121d-40bd-b763-342c697baeb8'	System	20 Oct 2020 16:09:20
User entered 'None (1)'	System	20 Oct 2020 16:09:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f2ee02f9-121d-40bd-b763-342c697baeb8'	System	20 Oct 2020 16:09:20
User entered 'No (N)'	System	20 Oct 2020 16:09:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:15', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f2ee02f9-121d-40bd-b763-342c697baeb8'	System	20 Oct 2020 16:09:20
User entered 'No (N)'	System	20 Oct 2020 16:09:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f2ee02f9-121d-40bd-b763-342c697baeb8'	System	20 Oct 2020 16:09:20
User entered 'None (1)'	System	20 Oct 2020 16:09:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:21', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f2ee02f9-121d-40bd-b763-342c697baeb8'	System	20 Oct 2020 16:09:20
User entered '20 Oct 2020 12:09'	System	20 Oct 2020 16:09:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 5'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e0e7d860-9b4b-4879-b384-e2acc3540199'	System	21 Oct 2020 23:28:21
User entered 'None (1)'	System	21 Oct 2020 23:28:21

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e0e7d860-9b4b-4879-b384-e2acc3540199'	System	21 Oct 2020 23:28:21
User entered 'No (N)'	System	21 Oct 2020 23:28:21

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:15', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e0e7d860-9b4b-4879-b384-e2acc3540199'	System	21 Oct 2020 23:28:21
User entered 'No (N)'	System	21 Oct 2020 23:28:21

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e0e7d860-9b4b-4879-b384-e2acc3540199'	System	21 Oct 2020 23:28:21
User entered 'None (1)'	System	21 Oct 2020 23:28:21

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:22', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e0e7d860-9b4b-4879-b384-e2acc3540199' User entered '21 Oct 2020 19:28'	System	21 Oct 2020 23:28:21
	System	21 Oct 2020 23:28:21

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 6'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:41', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2ca63e99-36e7-4fff-a09d-720e157048b1'	System	22 Oct 2020 19:42:53
User entered 'None (1)'	System	22 Oct 2020 19:42:53

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:44', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2ca63e99-36e7-4fff-a09d-720e157048b1'	System	22 Oct 2020 19:42:53
User entered 'No (N)'	System	22 Oct 2020 19:42:53

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2ca63e99-36e7-4fff-a09d-720e157048b1'	System	22 Oct 2020 19:42:53
User entered 'No (N)'	System	22 Oct 2020 19:42:53

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:51', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2ca63e99-36e7-4fff-a09d-720e157048b1'	System	22 Oct 2020 19:42:53
User entered 'None (1)'	System	22 Oct 2020 19:42:53

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:55', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '2ca63e99-36e7-4fff-a09d-720e157048b1'	System	22 Oct 2020 19:42:53
User entered '22 Oct 2020 15:42'	System	22 Oct 2020 19:42:53

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 7'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:06', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd6cc30d2-cb80-4cb6-80de-31c267d3651d'	System	23 Oct 2020 16:05:20
User entered 'None (1)'	System	23 Oct 2020 16:05:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:09', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd6cc30d2-cb80-4cb6-80de-31c267d3651d'	System	23 Oct 2020 16:05:20
User entered 'No (N)'	System	23 Oct 2020 16:05:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd6cc30d2-cb80-4cb6-80de-31c267d3651d'	System	23 Oct 2020 16:05:20
User entered 'No (N)'	System	23 Oct 2020 16:05:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:16', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd6cc30d2-cb80-4cb6-80de-31c267d3651d'	System	23 Oct 2020 16:05:20
User entered 'None (1)'	System	23 Oct 2020 16:05:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd6cc30d2-cb80-4cb6-80de-31c267d3651d' User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:05:20
	System	23 Oct 2020 16:05:20

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '24 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:09', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:12', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:17', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:23', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'None (0)'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered 'No (N)'	System	17 Oct 2020 16:33:36



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T12:33:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7937bf70-e638-4e01-af8c-9658a8cb24fa'	System	17 Oct 2020 16:33:36
User entered '17 Oct 2020 12:33'	System	17 Oct 2020 16:33:36

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 12:16'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 14:46'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 1, after vaccination (at home)'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:40', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'None (0)'	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:43', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'None (0)'	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f' User entered 'None (0)'	System	17 Oct 2020 21:07:08
	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:51', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'None (0)'	System	17 Oct 2020 21:07:08



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:55', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'None (0)'	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:06:58', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'None (0)'	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:07:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f'	System	17 Oct 2020 21:07:08
User entered 'No (N)'	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-17T17:07:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '045074db-305e-4f03-82ea-80a2633cb34f' User entered '17 Oct 2020 17:07'	System	17 Oct 2020 21:07:08
	System	17 Oct 2020 21:07:08

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 2'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:47', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:51', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:58:56', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:59:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:59:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'None (0)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:59:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered 'No (N)'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-18T13:59:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b477d1b2-8070-4dd4-9a8b-827306084e40'	System	18 Oct 2020 17:59:11
User entered '18 Oct 2020 13:59'	System	18 Oct 2020 17:59:11

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 3'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:14', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:17', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:22', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:25', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:29', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'None (0)'	System	19 Oct 2020 20:44:38



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:35', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered 'No (N)'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-19T16:44:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'e1b88e33-b9f3-4194-bf33-e77db1362cee'	System	19 Oct 2020 20:44:38
User entered '19 Oct 2020 16:44'	System	19 Oct 2020 20:44:38

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 4'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:31', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'None (0)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered 'No (N)'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-20T12:09:49', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '67899e90-46d8-4011-ac88-ec3ba7d10531'	System	20 Oct 2020 16:09:49
User entered '20 Oct 2020 12:09'	System	20 Oct 2020 16:09:49

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '20 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 5'	System	17 Oct 2020 16:28:56



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:30', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:39', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'None (0)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered 'No (N)'	System	21 Oct 2020 23:28:50

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-21T19:28:50', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '18545474-1186-42fd-ab6d-c2ad44c2f411'	System	21 Oct 2020 23:28:50
User entered '21 Oct 2020 19:28'	System	21 Oct 2020 23:28:50



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '21 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 6'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:42:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:02', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:05', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:10', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:12', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'None (0)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:17', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered 'No (N)'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-22T15:43:20', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '88e627b7-9f4b-42bb-93d1-7fa0aa627743'	System	22 Oct 2020 19:43:21
User entered '22 Oct 2020 15:43'	System	22 Oct 2020 19:43:21

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '22 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 11:59'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	17 Oct 2020 16:28:56
User entered 'Day 7'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:23', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:25', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56



US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:28', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered 'No (N)'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-23T12:03:49', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a5a0318e-3960-4ab7-9db7-7625a3eb4e5c'	System	23 Oct 2020 16:05:56
User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:05:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '23 Oct 2020 12:00'	System	17 Oct 2020 16:28:56

US3222388

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
User entered '24 Oct 2020 11:59'	System	17 Oct 2020 16:28:56



US3222388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:32

US3222388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '24 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:32

US3222388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4)	05 Nov 2020 19:08:32

US3222388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:32

US3222388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:38

US3222388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	05 Nov 2020 19:08:38

US3222388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:52

US3222388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '31 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:52



US3222388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:52

US3222388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:52

US3222388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 19:08:59

US3222388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	05 Nov 2020 19:08:59

US3222388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	15 Nov 2020 14:31:36

US3222388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '8 Nov 2020'	Crystal Paccione (b) (4)	15 Nov 2020 14:31:36

US3222388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	15 Nov 2020 14:31:36

US3222388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Crystal Paccione (b) (4)	15 Nov 2020 14:31:36



US3222388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 18:03:49

US3222388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:47
User entered 'I'	System	11 Nov 2020 18:03:49

US3222388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:03

US3222388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11 Nov 2020'	Albert Garcia (b) (4)	11 Nov 2020 18:04:03

US3222388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:03

US3222388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'VISIT3'	System	11 Nov 2020 18:04:03

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14



US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14



US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered empty.	System	11 Nov 2020 18:04:14

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57

US3222388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57

US3222388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'No (N)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:18



US3222388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 18:04:18

US3222388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:30

US3222388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11 Nov 2020'	Albert Garcia (b) (4)	11 Nov 2020 18:04:30

US3222388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered '11:19'	Albert Garcia (b) (4)	11 Nov 2020 18:04:30

US3222388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '11 Nov 2020 11:19'	System	11 Nov 2020 18:04:30

US3222388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 18:04:35

US3222388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered 'I'	System	11 Nov 2020 18:04:35

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 64'	System	28 Aug 2020 20:32:47



US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-28T00:01:59', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '762d847f-d918-4480-a43f-c1a36e9289c1'	System	28 Oct 2020 04:02:16
User entered 'No (N)'	System	28 Oct 2020 04:02:16

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-28T00:02:11', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '762d847f-d918-4480-a43f-c1a36e9289c1'	System	28 Oct 2020 04:02:16
User entered 'No (N)'	System	28 Oct 2020 04:02:16

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (176a88b187281e76)', Time: '2020-10-28T00:02:18', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '762d847f-d918-4480-a43f-c1a36e9289c1' User entered '28 Oct 2020 00:02:18'	System	28 Oct 2020 04:02:16
	System	28 Oct 2020 04:02:16

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 71'	System	28 Aug 2020 20:32:47

US3222388

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05



US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05



US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 20:32:47



US3222388

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:13:05
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered 'Day 78'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-11-11T03:08:48', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '4c2ee43d-1276-4d9b-a12a-c0401fcee180'	System	11 Nov 2020 08:09:01
User entered 'No (N)'	System	11 Nov 2020 08:09:01

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-11-11T03:08:54', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '4c2ee43d-1276-4d9b-a12a-c0401fcee180'	System	11 Nov 2020 08:09:01
User entered 'No (N)'	System	11 Nov 2020 08:09:01

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-11-11T03:09:02', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '4c2ee43d-1276-4d9b-a12a-c0401fcee180'	System	11 Nov 2020 08:09:01
User entered '11 Nov 2020 03:09:02'	System	11 Nov 2020 08:09:01

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 20:32:47

US3222388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:51
Data entry locked.	System	28 Aug 2020 20:32:47
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 20:32:47

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:13:05

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-03T16:34:48', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0d2fa99b-9ead-4a40-9fb1-c2586b2fcdf4'	System	03 Dec 2020 21:34:58
User entered 'No (N)'	System	03 Dec 2020 21:34:58

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-03T16:34:53', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0d2fa99b-9ead-4a40-9fb1-c2586b2fcdf4'	System	03 Dec 2020 21:34:58
User entered 'No (N)'	System	03 Dec 2020 21:34:58

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-03T16:35:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0d2fa99b-9ead-4a40-9fb1-c2586b2fcdf4'	System	03 Dec 2020 21:34:58
User entered '03 Dec 2020 16:35:00'	System	03 Dec 2020 21:34:58

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:13:05

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-07T14:44:32', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a6907207-d17a-4d0f-a6ea-498fa61a6e9d'	System	07 Dec 2020 19:44:38
User entered 'No (N)'	System	07 Dec 2020 19:44:38

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-07T14:44:36', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a6907207-d17a-4d0f-a6ea-498fa61a6e9d'	System	07 Dec 2020 19:44:38
User entered 'No (N)'	System	07 Dec 2020 19:44:38

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-07T14:44:40', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'a6907207-d17a-4d0f-a6ea-498fa61a6e9d'	System	07 Dec 2020 19:44:38
User entered '07 Dec 2020 14:44:40'	System	07 Dec 2020 19:44:38

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-14T00:15:07', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b116af30-f40c-4177-8422-ec1b8854d26f' User entered 'No (N)'	System	14 Dec 2020 05:15:26



US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-14T00:15:14', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b116af30-f40c-4177-8422-ec1b8854d26f'	System	14 Dec 2020 05:15:26
User entered 'No (N)'	System	14 Dec 2020 05:15:26

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2020-12-14T00:15:27', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'b116af30-f40c-4177-8422-ec1b8854d26f' User entered '14 Dec 2020 00:15:27'	System	14 Dec 2020 05:15:26
	System	14 Dec 2020 05:15:26

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-02-14T13:05:26', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '576743bc-c560-4fbd-9823-9d5ac2dff96c'	System	14 Feb 2021 18:07:53
User entered 'No (N)'	System	14 Feb 2021 18:07:53

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-02-14T13:05:33', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '576743bc-c560-4fbd-9823-9d5ac2dff96c'	System	14 Feb 2021 18:07:53
User entered 'No (N)'	System	14 Feb 2021 18:07:53

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-02-14T13:05:42', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '576743bc-c560-4fbd-9823-9d5ac2dff96c'	System	14 Feb 2021 18:07:53
User entered '14 Feb 2021 13:05:42'	System	14 Feb 2021 18:07:53



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:13:05

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-02T09:25:38', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0b121ff4-616d-4cc7-9e63-8740743a736a'	System	02 Mar 2021 14:25:55
User entered 'No (N)'	System	02 Mar 2021 14:25:55

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-02T09:25:45', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0b121ff4-616d-4cc7-9e63-8740743a736a'	System	02 Mar 2021 14:25:55
User entered 'No (N)'	System	02 Mar 2021 14:25:55



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-02T09:25:56', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '0b121ff4-616d-4cc7-9e63-8740743a736a'	System	02 Mar 2021 14:25:55
User entered '02 Mar 2021 09:25:56'	System	02 Mar 2021 14:25:55

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:13:05

US3222388

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-07T13:01:03', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '126ca596-3416-459b-b486-2d77d3dac3f8'	System	07 Mar 2021 18:02:08
User entered 'No (N)'	System	07 Mar 2021 18:02:08

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-07T13:01:12', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '126ca596-3416-459b-b486-2d77d3dac3f8'	System	07 Mar 2021 18:02:08
User entered 'No (N)'	System	07 Mar 2021 18:02:08

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-07T13:01:19', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '126ca596-3416-459b-b486-2d77d3dac3f8'	System	07 Mar 2021 18:02:08
User entered '07 Mar 2021 13:01:19'	System	07 Mar 2021 18:02:08

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:13:05

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-14T00:39:39-05:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4796bf7-24a0-4ca9-ae5a-9ce5308f696c'	System	14 Mar 2021 05:49:28
User entered 'No (N)'	System	14 Mar 2021 05:49:28

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-14T00:39:47-05:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4796bf7-24a0-4ca9-ae5a-9ce5308f696c'	System	14 Mar 2021 05:49:28
User entered 'No (N)'	System	14 Mar 2021 05:49:28

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-14T00:40:01-05:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'd4796bf7-24a0-4ca9-ae5a-9ce5308f696c'	System	14 Mar 2021 05:49:28
User entered '14 Mar 2021 00:40:01'	System	14 Mar 2021 05:49:28

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-23T03:34:00-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '24677868-70ee-4668-99fd-388e66455433'	System	23 Mar 2021 07:34:13
User entered 'No (N)'	System	23 Mar 2021 07:34:13

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-23T03:34:05-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '24677868-70ee-4668-99fd-388e66455433'	System	23 Mar 2021 07:34:13
User entered 'No (N)'	System	23 Mar 2021 07:34:13

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-23T03:34:10-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '24677868-70ee-4668-99fd-388e66455433'	System	23 Mar 2021 07:34:13
User entered '23 Mar 2021 03:34:10'	System	23 Mar 2021 07:34:13

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:13:05

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-30T18:57:13-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bc5e89c8-24f8-4f9c-87d9-a91303117b88'	System	30 Mar 2021 22:57:26
User entered 'No (N)'	System	30 Mar 2021 22:57:26

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-30T18:57:20-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bc5e89c8-24f8-4f9c-87d9-a91303117b88'	System	30 Mar 2021 22:57:26
User entered 'No (N)'	System	30 Mar 2021 22:57:26



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-30T18:57:25-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'bc5e89c8-24f8-4f9c-87d9-a91303117b88'	System	30 Mar 2021 22:57:26
User entered '30 Mar 2021 18:57:25'	System	30 Mar 2021 22:57:26

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-04T22:47:08-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f1dcd243-b55b-4471-9e0b-1ccb141d18fc' User entered 'No (N)'	System	05 Apr 2021 02:47:18
	System	05 Apr 2021 02:47:18

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-04T22:47:13-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f1dcd243-b55b-4471-9e0b-1ccb141d18fc' User entered 'No (N)'	System	05 Apr 2021 02:47:18
	System	05 Apr 2021 02:47:18

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-04T22:47:17-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: 'f1dcd243-b55b-4471-9e0b-1ccb141d18fc' User entered '04 Apr 2021 22:47:17'	System	05 Apr 2021 02:47:18
	System	05 Apr 2021 02:47:18

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:13:05

US3222388

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-22T13:21:10-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7e6aa432-3180-41f0-a621-72d8e85e1725' User entered 'No (N)'	System	22 Apr 2021 17:21:36
	System	22 Apr 2021 17:21:36

US3222388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-22T13:21:19-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7e6aa432-3180-41f0-a621-72d8e85e1725'	System	22 Apr 2021 17:21:36
User entered 'No (N)'	System	22 Apr 2021 17:21:36

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-04-22T13:21:30-04:00', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '7e6aa432-3180-41f0-a621-72d8e85e1725' User entered '22 Apr 2021 13:21:30'	System	22 Apr 2021 17:21:36
	System	22 Apr 2021 17:21:36



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:13:05



**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:13:05

**US3222388**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:13:05
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:13:05

US3222388

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:03:07**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-02T09:25:13', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '19f9415e-81f5-414b-90a5-f41821390047'	System	02 Mar 2021 14:25:22
User entered 'No (N)'	System	02 Mar 2021 14:25:22

US3222388

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ca25448e2495022)', Time: '2021-03-02T09:25:24', User OID: 'PatientReportedOutcome (US3222388)', ODM File OID: '19f9415e-81f5-414b-90a5-f41821390047'	System	02 Mar 2021 14:25:22
User entered '02 Mar 2021 09:25:24'	System	02 Mar 2021 14:25:22

US3222388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 20:55:53
User entered 'Yes (Y)' reason for change: Data Entry Error	heather jackson (b) (4)	14 Dec 2020 20:55:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	07 Dec 2020 16:22:35
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	07 Dec 2020 16:22:35
	(b) (4)	
	Alicia Cevera (b) (4)	07 Dec 2020 16:16:37
	(b) (4)	

US3222388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Dec 2020 20:57:25
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	14 Dec 2020 20:57:25
User entered '09 Dec 2020' reason for change: Data Entry Error	heather jackson (b) (4)	14 Dec 2020 20:57:25
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Dec 2020 20:55:53
User entered '18 Nov 2020' reason for change: Data Entry Error	heather jackson (b) (4)	14 Dec 2020 20:55:53
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Dec 2020 16:22:35
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	07 Dec 2020 16:22:35
User entered empty; reason for change Data Entry Error	Alicia Cevera (b) (4)	07 Dec 2020 16:22:35
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Dec 2020 16:16:37
User entered '18 Nov 2020'	Alicia Cevera (b) (4)	07 Dec 2020 16:16:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1533 of 2174

US3222388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	14 Dec 2020 20:55:53
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Alicia Cevera (b) (4)	07 Dec 2020 16:22:35
User entered 'Contact Made (CONTACT MADE)'	Alicia Cevera (b) (4)	07 Dec 2020 16:16:37
	(b) (4)	

US3222388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User entered empty.	(b) (4) Alicia Cevera (b) (4)	07 Dec 2020 16:16:37



US3222388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:05:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 20:57:30
User entered 'Yes (Y)' reason for change: Data Entry Error	heather jackson (b) (4)	14 Dec 2020 20:57:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	07 Dec 2020 16:22:42
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	07 Dec 2020 16:22:42
	(b) (4)	
	Alicia Cevera (b) (4)	07 Dec 2020 16:16:45
	(b) (4)	

US3222388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:34:57
User entered '1'	System	14 Dec 2020 20:57:30
User entered empty.	System	07 Dec 2020 16:22:42
User entered '1'	System	07 Dec 2020 16:16:45

US3222388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:38:00

US3222388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:38:00

US3222388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:38:00

US3222388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:38:00

US3222388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:38:05

US3222388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User entered 'I'	System	12 Jan 2021 16:38:05



US3222388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Feb 2021 21:27:18

US3222388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	29 Mar 2021 17:53:58
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	29 Mar 2021 17:53:58
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 17:53:58
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	13 Feb 2021 21:27:18
User entered '09 Feb 2021'	(b) (4), (b) (6)	13 Feb 2021 21:27:18

US3222388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Feb 2021 21:27:18

US3222388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Feb 2021 21:27:18

US3222388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 16:11:22

US3222388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User entered 'I'	System	27 Mar 2021 16:11:22

US3222388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 16:12:35

US3222388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:32:16
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '-17 days oow. recorded on protocol deviation form' (Site from System).		27 Mar 2021 16:23:43
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Mar 2021 16:12:35
User entered '24 Feb 2021'	(b) (4), (b) (6)	27 Mar 2021 16:12:35



US3222388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 16:12:35

US3222388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'unable to get in contact with subject. Voicemail not set up.'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 16:12:35

US3222388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Mar 2021 16:23:48

US3222388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:20:02
User entered 'I'	System	27 Mar 2021 16:23:48

US3222388

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:03:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:16
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:57:13
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:19:06

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	04 Nov 2020 21:10:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 18:47:24
User entered	System	09 Oct 2020 18:47:14
'USA-US104-2020-mRNA-1273-P301000009'		
User entered 'New' reason for change: Data Entry	(b) (4), (b) (6)	09 Oct 2020 18:47:14
Error		
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:45:01

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4)	08 Apr 2021 15:24:40
User closed query 'PV Query: As subject had history of multilevel foraminal lumbar stenosis, please confirm if event term should be updated to 'worsening of multilevel foraminal lumbar stenosis.' ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:29:01
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'degenerative and not worsening' (Site from DM).		07 Apr 2021 12:59:19
Query 'PV Query: As subject had history of multilevel foraminal lumbar stenosis, please confirm if event term should be updated to 'worsening of multilevel foraminal lumbar stenosis.' ' answered with 'per hospital records this was degenerative and not worsening' (Site from Safety).		07 Apr 2021 12:59:03
User opened query 'PV Query: As subject had history of multilevel foraminal lumbar stenosis, please confirm if event term should be updated to 'worsening of multilevel foraminal lumbar stenosis.' ' (Site from Safety).		06 Apr 2021 11:56:51
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).		03 Apr 2021 05:47:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Vertebral foraminal stenosis, LLT: Lumbar foraminal stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:35:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:35:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1558 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Mar 2021 18:47:06
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 18:46:36
User entered 'Lumbar canal and foramina stenosis'		29 Mar 2021 18:46:36
reason for change: Data Entry Error		
User closed query 'PV Query: Please consider		16 Nov 2020 19:47:26
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
User coded data point as SOC: Injury, poisoning and	Coder Import (b) (4)	15 Nov 2020 10:27:41
procedural complications, HLGT: Injuries NEC,	(b) (4)	
HLT: Non-site specific injuries NEC, PT: Fall, LLT:		
Fall - version MedDRA\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Nov 2020 10:27:41
User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	15 Nov 2020 10:26:48
Query 'PV Query: Please consider updating the event	douglas winter (b) (4)	15 Nov 2020 10:26:28
term to the underlying cause/etiology of the event.'	(b) (4)	
answered with 'UPDATED' (Site from Safety).		
Coding entries removed.	douglas winter (b) (4)	15 Nov 2020 10:26:19
	(b) (4)	
User entered 'FALL' reason for change: Data Entry	douglas winter (b) (4)	15 Nov 2020 10:26:19
Error	(b) (4)	
User opened query 'PV Query: Please consider	(b) (4), (b) (6)	13 Nov 2020 16:24:32
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
User closed query 'PV Query: Please consider		06 Nov 2020 17:54:07
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
Query 'PV Query: Please consider updating the event	douglas winter (b) (4)	05 Nov 2020 19:18:51
term to the underlying cause/etiology of the event.'	(b) (4)	
answered with 'UPDATED TERM PER PATIENT		
SINCE WE DONT HAVE MEDICAL RECORDS		
YET. STILL PENDING.' (Site from Safety).		
User coded data point as SOC: Surgical and medical	Coder Import (b) (4)	05 Nov 2020 19:18:24
procedures, HLGT: Nervous system, skull and spine	(b) (4)	
therapeutic procedures, HLT: Spine and spinal cord		
therapeutic procedures, PT: Spinal fusion surgery,		
LLT: Fusion lumbar spine - version MedDRA\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Nov 2020 19:18:24
User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 19:17:24



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	douglas winter (b) (4)	05 Nov 2020 19:16:59
	(b) (4)	
Coding entries removed.	douglas winter (b) (4)	05 Nov 2020 19:16:59
	(b) (4)	
User entered 'LUMBAR SPINAL FUSION' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 19:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:10:41
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).		19 Oct 2020 14:06:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:30:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:30:30
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 15:29:54
User entered 'BACK SURGERY'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:20
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:06:34
		16 Nov 2020 02:40:01
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:17:57
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:17:49
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:18:09
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:46
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:51
User entered '25 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:49
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:03:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:54
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: The end date for the event, fall, was reported as 25 Sep 2020. The subject was discharged from the hospital on 30 Sep 2020. Please confirm event end date and/or provide the reason why the subject remained hospitalized even after the event resolved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:25:32
Query 'PV Query: The end date for the event, fall, was reported as 25 Sep 2020. The subject was discharged from the hospital on 30 Sep 2020. Please confirm event end date and/or provide the reason why the subject remained hospitalized even after the event resolved.' answered with 'patient in hospital for laminectomy' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:04:58
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 17:03:55
User opened query 'PV Query: The end date for the event, fall, was reported as 25 Sep 2020. The subject was discharged from the hospital on 30 Sep 2020. Please confirm event end date and/or provide the reason why the subject remained hospitalized even after the event resolved.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:41:18
User closed query 'Per DM CLR: Please review the stop date of this AE as it is unexpected for FALL to last for more than 1 day. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 11:04:57
Query 'Per DM CLR: Please review the stop date of this AE as it is unexpected for FALL to last for more than 1 day. Review and update AE eCRF as appropriate.' answered with 'CORRECTED DATE TO 25' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 14:01:49
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	06 Mar 2021 14:01:31
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Mar 2021 14:01:31
User opened query 'Per DM CLR: Please review the stop date of this AE as it is unexpected for FALL to last for more than 1 day. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:40:38
DataPoint Verified.		04 Nov 2020 21:11:57

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:32:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Oct 2020 15:32:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:29:42
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:59
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:03:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:01
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:04
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:12:07
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:16
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:12:18
User entered 'I'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20
User entered '25 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:22
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:27
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:32
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:33
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:12:38
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:49
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:58
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:32
User closed query 'Per source, action was None. Please verify and update accordingly.' (Site from CRA).		16 Nov 2020 02:40:29
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 10:26:57
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	15 Nov 2020 10:25:51
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:25:03
Query 'Per source, action was None. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:15:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:15:22
User opened query 'Per source, action was None. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:13:41
User entered 'Dose Delayed (DOSE DELAYED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:13:46
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: RQ: Responses noted, however, please update the corresponding Con Med indications to match the AE term as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	08 Apr 2021 15:23:30
Query 'Per DM CLR: RQ: Responses noted, however, please update the corresponding Con Med indications to match the AE term as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:16:36
User opened query 'Per DM CLR: RQ: Responses noted, however, please update the corresponding Con Med indications to match the AE term as appropriate. Otherwise, clarify.' (Site from DM).		03 Apr 2021 05:49:32
User closed query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you ' (Site from DM).		31 Mar 2021 08:33:37
Query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you ' answered with 'please see conmed page loglines 8,9,10,11,12' (Site from DM).		29 Mar 2021 18:10:02
User opened query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you ' (Site from DM).		08 Mar 2021 11:16:09
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		08 Mar 2021 11:16:09
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATING CONMED PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 17:59:00

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:20:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		23 Nov 2020 01:20:07
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'RECORDS PENDING' (Site from DM).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:13:49
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		01 Nov 2020 02:18:18
User entered 'I'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'updated as therapeutic' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:33:48  29 Mar 2021 18:11:32  22 Mar 2021 09:55:54
DataPoint Un-verified.	douglas winter (b) (4)	06 Mar 2021 17:59:24
User entered '1' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	06 Mar 2021 17:59:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:09
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:16:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4)	09 Oct 2020 15:32:22
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4)	09 Oct 2020 15:31:54
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4)	09 Oct 2020 15:29:42
	(b) (4)	



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:16:53
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: CT abdomen pelvis results were recently removed from narrative details. Please confirm if this is correct or should be retained as part of full results. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:29:33
User closed query 'PV Query: Please provide date of lumbar spinal fusion surgery and laminectomy. If unknown, please indicate so. ' (Site from Safety).		08 Apr 2021 13:29:22
Query 'PV Query: CT abdomen pelvis results were recently removed from narrative details. Please confirm if this is correct or should be retained as part of full results. ' answered with 'Ct abdomen and pelvis was completed but not related to this SAE' (Site from Safety).		07 Apr 2021 13:16:20
Query 'PV Query: Please provide date of lumbar spinal fusion surgery and laminectomy. If unknown, please indicate so. ' answered with 'date of surgery 9/25/20' (Site from Safety).		07 Apr 2021 13:15:04
User opened query 'PV Query: CT abdomen pelvis results were recently removed from narrative details. Please confirm if this is correct or should be retained as part of full results. ' (Site from Safety).		06 Apr 2021 11:57:25
User opened query 'PV Query: Please provide date of lumbar spinal fusion surgery and laminectomy. If unknown, please indicate so. ' (Site from Safety).		06 Apr 2021 11:57:15
User closed query 'Per DM CLR: Narrative indicates that the subject had Abdominal Pain, Possible Infiltration of the Liver, Cholelithiasis, Splenic Calcifications, Hiatal Hernia, Colonic Diverticula, Advanced Multilevel Degenerative Changes and Spondylosis of the Lumbar Spine, Bilateral Foraminal Stenosis, Facet Arthropathy and Spinal Canal Stenosis. However, there are no recorded AE that match the information. Please update to record the AEs as appropriate. Otherwise, clarify.' (Site from DM).		31 Mar 2021 08:34:12

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = NEURAL FORAMINA L4-5 MODERATE BILATERAL FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY / SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS / CANAL STENOSIS AND FORAMINAL STENOSIS. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:34:09
User closed query 'Per DM CLR: SAE Narrative = CT LUMBAR SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		31 Mar 2021 08:34:05
User closed query 'Per DM CLR: SAE Narrative = COLONIC DIVERTICULA WITHOUT EVIDENCE OF DIVERTICULITIS / MILD CIRCUMFERENTIAL URINARY BLADDER WALL THICKENING MAY BE DUE TO SUBOPTIMAL DISTENTION ALTHOUGH CYSTITIS IS NOT EXCLUDED. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		31 Mar 2021 08:34:02
User closed query 'Per DM CLR: SAE Narrative = CT ABDOMEN PELVIS W/CONTRAST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		31 Mar 2021 08:33:59
User closed query 'PV Query: Please provide an event which was treated by the lumbar spine fusion surgery.' (Site from Safety).		30 Mar 2021 16:25:51

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 16:25:44
User closed query 'PV Query:Please confirm that 'multilevel degenerative changed spondylosis of the lumbar spine with multilevel foraminal stenosis' meets criteria of SAE/AE. If not, please explain.' (Site from Safety).		30 Mar 2021 16:25:38
Query 'Per DM CLR: Narrative indicates that the subject had Abdominal Pain, Possible Infiltration of the Liver, Cholelithiasis, Splenic Calcifications, Hiatal Hernia, Colonic Diverticula, Advanced Multilevel Degenerative Changes and Spondylosis of the Lumbar Spine, Bilateral Foraminal Stenosis, Facet Arthropathy and Spinal Canal Stenosis. However, there are no recorded AE that match the information. Please update to record the AEs as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		29 Mar 2021 18:49:24
Query 'Per DM CLR: SAE Narrative = NEURAL FORAMINA L4-5 MODERATE BILATERAL FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY / SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS / CANAL STENOSIS AND FORAMINAL STENOSIS. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated and corrected' (Site from DM).		29 Mar 2021 18:49:05
Query 'Per DM CLR: SAE Narrative = CT LUMBAR SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated and added' (Site from DM).		29 Mar 2021 18:48:51

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1595 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = COLONIC DIVERTICULA WITHOUT EVIDENCE OF DIVERTICULITIS / MILD CIRCUMFERENTIAL URINARY BLADDER WALL THICKENING MAY BE DUE TO SUBOPTIMAL DISTENTION ALTHOUGH CYSTITIS IS NOT EXCLUDED. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated and corrected' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:48:42
Query 'Per DM CLR: SAE Narrative = CT ABDOMEN PELVIS W/CONTRAST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:48:25
Query 'PV Query:Please confirm that 'multilevel degenerative changed spondylosis of the lumbar spine with multilevel foraminal stenosis' meets criteria of SAE/AE. If not, please explain.' answered with 'updated per medical records' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:48:14
Query 'PV Query: Please provide an event which was treated by the lumbar spine fusion surgery.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:47:52

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAMINAL STENOSIS.  1. STATUS POST POSTERIOR DECOMPRESSION AT L3-S1 2. LUMBAR SPINE NO ACUTE FRACTURE 3. NO FOCAL ALIGNMENT ABNORMALITIES 4. NEURAL FORAMINA L4-5 MODERATE BILATERAL FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY 5. SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS.  6. NO ACUTE FRACTURE IN THE LUMBAR SPINE 7. CANAL STENOSIS AND FORAMINAL STENOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:47:44
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'no COVID testing documented in hospital records ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:36:46

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAMINAL STENOSIS.  1. CT LUMBAR SPINE FROM A FALL FINDINGS 1. STATUS POST POSTERIOR DECOMPRESSION AT L3-S1 2. LUMBAR SPINE NO ACUTE FRACTURE 3. NO FOCAL ALIGNMENT ABNORMALITIES 4. NEURAL FORAMINA L4-5 MODERATE BILATERAL FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY 5. SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS.  6. NO ACUTE FRACTURE IN THE LUMBAR SPINE 7. CANAL STENOSIS AND FORAMINAL STENOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:35:49
User closed query 'PV Query: The CT of lumbar spine showed status post posterior decompression at L3-S1. Please list a relevant disease in the medical history.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:38:46
User closed query 'PV Query: Please clarify whether abdominal pain, mild fatty infiltration of the liver, cholelithiasis, and hiatus hernia meet definition of AE/SAE. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:38:43
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:38:41
User closed query 'Per DM CLR: SAE Narrative = BACK SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 11:25:02

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The CT of lumbar spine showed status post posterior decompression at L3-S1. Please list a relevant disease in the medical history.' answered with 'ADDED TO HISTORY PAGE' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:32:36
Query 'PV Query: Please clarify whether abdominal pain, mild fatty infiltration of the liver, cholelithiasis, and hiatus hernia meet definition of AE/SAE. ' answered with 'COMPLETED AE'S FOR THE FOLLOWING...abdominal pain, mild fatty infiltration of the liver, cholelithiasis, and hiatus hernia ' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:24:20
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' answered with 'ACCIDENTAL FALL' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:23:22
Query 'Per DM CLR: SAE Narrative = BACK SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED AE TO CAPTURE CONPROC' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:01:19
User opened query 'Per DM CLR: Narrative indicates that the subject had Abdominal Pain, Possible Infiltration of the Liver, Cholelithiasis, Splenic Calcifications, Hiatal Hernia, Colonic Diverticula, Advanced Multilevel Degenerative Changes and Spondylosis of the Lumbar Spine, Bilateral Foraminal Stenosis, Facet Arthropathy and Spinal Canal Stenosis. However, there are no recorded AE that match the information. Please update to record the AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	13 Jan 2021 11:00:12



US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = NEURAL FORAMINA L4-5 MODERATE BILATERAL FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY / SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS / CANAL STENOSIS AND FORAMINAL STENOSIS. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:46:33
User opened query 'Per DM CLR: SAE Narrative = CT LUMBAR SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		08 Dec 2020 02:45:48
User opened query 'Per DM CLR: SAE Narrative = COLONIC DIVERTICULA WITHOUT EVIDENC OF DIVERTICULITIS / MILD CIRCUMFERENTIAL URINARY BLADDER WALL THICKENING MAY BE DUE TO SUBOPTIMAL DISTENTION ALTHOUGH CYSTITIS IS NOT EXCLUDED. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		08 Dec 2020 02:45:41
User opened query 'Per DM CLR: SAE Narrative = CT ABDOMEN PELVIS W/CONTRAST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		08 Dec 2020 02:44:03
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).		25 Nov 2020 16:21:12

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1600 of 2174

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query:Please confirm that 'multilevel degenerative changed spondylosis of the lumbar spine with multilevel foraminal stenosis' meets criteria of SAE/AE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:21:00
User opened query 'PV Query: Please provide an event which was treated by the lumbar spine fusion surgery.' (Site from Safety).		25 Nov 2020 16:20:48
User opened query 'PV Query: The CT of lumbar spine showed status post posterior decompression at L3-S1. Please list a relevant disease in the medical history.' (Site from Safety).		25 Nov 2020 16:20:32
User opened query 'PV Query: Please clarify whether abdominal pain, mild fatty infiltration of the liver, cholelithiasis, and hiatus hernia meet definition of AE/SAE. ' (Site from Safety).		25 Nov 2020 16:19:36
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).		25 Nov 2020 16:19:24
User opened query 'Per DM CLR: SAE Narrative = BACK SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that thi is captured in the appropriate eCRF. ' (Site from DM).		23 Nov 2020 01:19:27
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		16 Nov 2020 19:47:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		16 Nov 2020 19:47:38
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		16 Nov 2020 19:47:36

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'waiting on hospital records for this information' (Site from Safety).	Crystal Paccione (b) (4)	15 Nov 2020 14:50:05
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UPDATED CONMED PAGE' (Site from Safety).	douglas winter (b) (4)	15 Nov 2020 11:49:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UPDATED NARRATIVE' (Site from Safety).	douglas winter (b) (4)	15 Nov 2020 11:49:42
DataPoint Un-verified.	douglas winter (b) (4)	15 Nov 2020 11:49:18

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED ME YESTERDAY AT 30/SEP/2020 AT 14:26 HRS THAT HE WAS IN THE HOSPITAL FROM 25/SEP/2020 TO 30/SEP/2020 FOR AN UNKNOWN TYPE OF BACK SURGERY.  SUBJECT NOTIFIED ME YESTERDAY AT 30/SEP/2020 AT 14:26 HRS THAT HE WAS IN THE HOSPITAL FROM 25/SEP/2020 TO 30/SEP/2020 FOR AN UNKNOWN TYPE OF BACK SURGERY. I STILL HAVE NOT RECEIVED RECORDS FROM THE HOSPITAL HE ATTENDED, AND SO I ARRANGED FOR THE PATIENT TO BRING IN THE RECORDS HE RECEIVED UPON DISCHARGE.  59 YEAR OLD MALE WITH ABDOMINAL PAIN DIAGNOSTICS 1. CT ABDOMEN PELVIS W/CONTRAST IMPRESSION 1. POSSIBLE MILD FATTY INFILTRATION OF THE LIVER 2. CHOLELITHIASIS 3. SPLENIC CALCIFICATIONS IN KEEPING WITH OLD HEALED GRANULOMATOUS DISEASE 4. SMALL HIATUS HERNIA 5. COLONIC DIVERTICULA WITHOUT EVIDENCE OF DIVERTICULITIS 6. MILD CIRCUMFERENTIAL URINARY BLADDER WALL THICKENING MAY BE DUE TO SUBOPTIMAL DISTENTION ALTHOUGH CYSTITIS IS NOT EXCLUDED. 7. NO FREE INTRAPERITONEAL AIR FLUID. NO ABDOMIOPELVIC LYMPHADENOPATHY 8. ADVANCED MULTILEVEL DEGENERATIVE CHANGES AND SPONDYLOSIS OF THE LUMBAR SPINE WITH MULTILEVEL FORAMINAL STENOSIS.  1. CT LUMBAR SPINE FROM A FALL FINDINGS 1. STATUS POST POSTERIOR DECOMPRESSION AT L3-S1 2. LUMBAR SPINE NO ACUTE FRACTURE 3. NO FOCAL ALIGNMENT ABNORMALITIES 4. NEURAL FORAMINA L4-5 MODERATE BILATERAL	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:49:18

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
FORAMINAL STENOSIS FROM ADJACENT SEVERE LOSS OF DISC HEIGHT, POSTERIOR SPONDYLOSIS AND FACET ARTHROPATHY 5. SPINAL CANAL, POSTERIOR SPONDYLOSIS, LIGAMENTUM FLAVUM HYPERTROPHY AND FACET ARTHROPATHY LIKELY CONTRIBUTING TO L1-2 MILD CANAL STENOSIS, AN DL2-3 MILD TO MODERATE CANAL STENOSIS.  6. NO ACUTE FRACTURE IN THE LUMBAR SPINE 7. CANAL STENOSIS AND FORAMINAL STENOSIS' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:46
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		13 Nov 2020 16:24:40
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).		13 Nov 2020 16:24:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		06 Nov 2020 17:54:23
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		06 Nov 2020 17:54:20

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RECORDS PENDING' (Site from Safety).	douglas winter (b) (4)	05 Nov 2020 19:17:20
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'RECORDS PENDING' (Site from Safety).	douglas winter (b) (4)	05 Nov 2020 19:17:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:17:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		19 Oct 2020 14:07:08
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).		19 Oct 2020 14:05:28
User entered 'SUBJECT NOTIFIED ME YESTERDAY AT 30/SEP/2020 AT 14:26 HRS THAT HE WAS IN THE HOSPITAL FROM 25/SEP/2020 TO 30/SEP/2020 FOR AN UNKNOWN TYPE OF BACK SURGERY. I WILL REQUEST RECORDS.'	douglas winter (b) (4)	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 15:29:42

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:29:42



**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 15:29:42

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:17:56
Reviewed for Safety.		09 Oct 2020 18:48:30
User entered 'USA-US104-2020-mRNA-1273-P301000009'		09 Oct 2020 18:48:25

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incision site pain, LLT: Incision site pain - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 19:22:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 19:22:39
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of PAIN AT SURGERY SITE. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:31:08
Data point term sent to Coder	System	05 Nov 2020 19:49:49
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of PAIN AT SURGERY SITE. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4)	05 Nov 2020 19:49:48
Coding entries removed.	douglas winter (b) (4)	05 Nov 2020 19:48:52
User entered 'LUMBAR PAIN AT SURGERY SITE.' reason for change: Data Entry Error DataPoint Un-verified.	douglas winter (b) (4)	05 Nov 2020 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:18:13
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of PAIN AT SURGERY SITE. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).		04 Nov 2020 21:17:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incision site pain, LLT: Incision site pain - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 02:18:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 17:13:21

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Oct 2020 15:57:42
User entered 'PAIN AT SURGERY SITE.'	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:18:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:40:47
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).		06 Nov 2020 18:31:14
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:49:59
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:48:52
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:18:39
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:18:39
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:18:41
User entered '8 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51



US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:18:44
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:03:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:40:56
User closed query 'Per source, Subject returned to Site 17Oct20 for D29 visit, no AEs reported, please verify if SAE is ongoing.' (Site from CRA).		16 Nov 2020 02:40:54
Query 'Per source, Subject returned to Site 17Oct20 for D29 visit, no AEs reported, please verify if SAE is ongoing.' answered with 'UPDDATED' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:50:15
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:41:22
User opened query 'Per source, Subject returned to Site 17Oct20 for D29 visit, no AEs reported, please verify if SAE is ongoing.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:23:44
Query 'Per source, Subject was discharged 13Oct20 from hospital. Subject returned to Site 17Oct20 for D29 visit, no AEs reported, please update AE end date' canceled (Site from CRA).		04 Nov 2020 21:23:06
User opened query 'Per source, Subject was discharged 13Oct20 from hospital. Subject returned to Site 17Oct20 for D29 visit, no AEs reported, please update AE end date' (Site from CRA).		04 Nov 2020 21:21:37
DataPoint Un-verified.		04 Nov 2020 21:20:12
DataPoint Verified.		04 Nov 2020 21:18:45
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:54:43
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 'ADDED END DATE' (Site from Safety).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:50:26
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 19:49:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Nov 2020 19:49:31
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 19:41:22
User entered '9 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:41:22
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 21:20:22
DataPoint Verified.		04 Nov 2020 21:18:48
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).		19 Oct 2020 14:09:27
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:21:53
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:21:55
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51



US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:22:00
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:21:57
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:22:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		27 Oct 2020 08:52:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'SUBJECT IS STILL IN THE HOSPITAL.' (Site from System).	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:58:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Oct 2020 15:56:51
User entered 'I'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:22:04
User entered '8 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per source subject was discharged 13Oct20. Please verify and update accordingly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:41:06
User closed query 'PV Query: Please provide hospital discharge date, when available. ' (Site from Safety).		06 Nov 2020 17:54:48
Query 'Per source subject was discharged 13Oct20. Please verify and update accordingly. ' answered with '13OCT2020 IS WHEN I SENT FOR MEDICAL RECORDS.' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:51:11
Query 'PV Query: Please provide hospital discharge date, when available. ' answered with 'ADDED DISCHARGE DATE' (Site from Safety).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:50:45
User entered '9 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:48:52
User opened query 'Per source subject was discharged 13Oct20. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:22:55
User opened query 'PV Query: Please provide hospital discharge date, when available. ' (Site from Safety).		19 Oct 2020 14:09:54
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:04
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:06
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51



US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:08
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:10
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:13
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:30
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:25:36
User entered 'Dose Delayed (DOSE DELAYED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:25:38
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: Please provide any treatment for the event, lumbar pain at surgery site. ' (Site from Safety).	(b) (4)	08 Apr 2021 13:29:54
Query 'PV Query: Please provide any treatment for the event, lumbar pain at surgery site. ' answered with 'continued pain medication' (Site from Safety).	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide any treatment for the event, lumbar pain at surgery site. ' (Site from Safety).		
User closed query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).		
Query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' answered with 'please see con med page log lines 8,9,10, 11, 12' (Site from DM).		
User opened query 'Per CDM: Per previous query response "UPDATING CONMED PAGE"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).		
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'UPDATING CONMED PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:00:17

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:21:06
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		23 Nov 2020 01:21:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'RECORDS STILL PENDING' (Site from DM).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:25:47
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		01 Nov 2020 02:18:49
User entered 'I'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51



US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	06 Mar 2021 18:00:48
	(b) (4)	
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 18:00:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:25:52
User entered '0'	douglas winter (b) (4)	09 Oct 2020 15:56:51
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:54:53
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:51:36
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:49:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:49:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:25:58
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).		19 Oct 2020 14:08:30
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:26:00
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:55:01
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		06 Nov 2020 17:54:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RECORDS STILL PENDING' (Site from Safety).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:52:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'RECORDS STILL PENDING' (Site from Safety).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:52:02
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:26:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		19 Oct 2020 14:08:54
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		19 Oct 2020 14:08:43

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED ME TODAY @ 13:33 THAT HE IS BACK IN THE HOSPITAL FOR LOWER BACK PAIN AT THE SURGICAL SITE. HE ARRIVED YESTERDAY AND MAY BE RELEASED TOMORROW AND WILL CALL ME WHEN HE IS DISCHARGED.'	douglas winter (b) (4)	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:56:51

US3222388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:03:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:56:51

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 15:56:51



US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Uncontrolled hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 17:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 17:59:03
Data point term sent to Coder	System	06 Mar 2021 17:57:59
User entered 'UNCONTROLLED HYPERTENSION'	douglas winter (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4)	06 Mar 2021 17:57:33
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered empty.	System	06 Mar 2021 17:57:33



US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:34:59
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated per records' (Site from DM).		29 Mar 2021 17:58:30
User entered 'No (N)' reason for change: Data Entry Error		29 Mar 2021 17:58:05
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		22 Mar 2021 09:58:40
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:58:05
User entered empty.	douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered empty.	System	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:25:18
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.'		07 Apr 2021 13:10:51
answered with 'updated' (Site from DM).		
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		07 Apr 2021 13:10:24
reason for change: Data Entry Error		
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).		03 Apr 2021 05:50:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 17:57:42
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 17:57:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Mar 2021 17:57:33
	douglas winter (b) (4)	06 Mar 2021 17:57:33
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33



US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33



US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	29 Mar 2021 17:58:05
Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4)	06 Mar 2021 17:57:33
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

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 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33



US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered '0'	System	06 Mar 2021 17:57:42

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered '1'	System	06 Mar 2021 17:57:33

US3222388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Colonic diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 10:49:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 10:49:08
Data point term sent to Coder	System	06 Mar 2021 18:13:19
User entered 'ABDOMINAL PAIN (COLONIC DIVERTICULA)'	douglas winter (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Mar 2021 18:20:31
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Mar 2021 18:12:56
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:12:56



US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '1 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered empty.	System	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:35:15
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'procedure was diagnostic and not therapeutic. conmed was prescribed for treatment' (Site from DM).		29 Mar 2021 18:02:46
User entered 'No (N)' reason for change: Data Entry Error		29 Mar 2021 18:02:27
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		22 Mar 2021 09:59:00
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:02:27
User entered empty.	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered empty.	System	06 Mar 2021 18:12:56



US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56



US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	06 Mar 2021 18:17:03
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 18:17:03
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	06 Mar 2021 18:16:56
User entered '1'	douglas winter (b) (4)	06 Mar 2021 18:12:56



US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
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). 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 'no documentation' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:47:55
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). User entered '1' reason for change: Data Entry Error		07 Apr 2021 13:12:12
		07 Apr 2021 13:11:21
		03 Apr 2021 05:51:03
		29 Mar 2021 18:02:27
User entered '0'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4)	31 Mar 2021 08:35:20
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'procedure was diagnostic and not therapeutic. conmed was prescribed for treatment' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:03:00
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:59:14
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 18:16:56
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:02:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4)	06 Mar 2021 18:12:56
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

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 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'WITHOUT EVIDENCE OF DIVERTICULITIS. THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. NOT TREATED AFTER DISCOVERY.' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:20:31
User entered 'WITHOUT EVIDENCE OF DIVERTICULITIS. THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:56
User entered 'WITHOUT EVIDENCE OF DIVERTICULITIS'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered '0'	System	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19
User entered '0'	System	06 Mar 2021 18:20:31
User entered '1'	System	06 Mar 2021 18:12:56

US3222388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:47:19



US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatus hernia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 18:17:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 18:17:04
	(b) (4)	
Data point term sent to Coder	System	06 Mar 2021 18:16:20
User entered 'HIATUS HERNIA'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 18:19:54
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '14 Sep 2020'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06



US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:03:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06



US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06



US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	06 Mar 2021 18:16:17
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 18:16:17
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	06 Mar 2021 18:16:06
User entered '1'	douglas winter (b) (4)	06 Mar 2021 18:16:06
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:35:43
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'procedure was diagnostic and not therapeutic.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:04:13
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:59:31
User entered 'I'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. NOT TREATED AFTER DISCOVERY.' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:54
User entered 'THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C.'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:16:06



**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:16:06

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:19:54
User entered '1'	System	06 Mar 2021 18:16:06

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 18:35:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 18:35:04
	(b) (4)	
Data point term sent to Coder	System	06 Mar 2021 18:19:22
User entered 'CHOLELITHIASIS'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '14 Sep 2020'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22



**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:03:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:03:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	



US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22



US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'procedure was diagnostic and not therapeutic. ' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:38:10  29 Mar 2021 18:05:16  22 Mar 2021 09:59:49
	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:19:22



US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:19:22
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. NOT TREATED AFTER DISCOVERY.'	(b) (4) douglas winter (b) (4)	06 Mar 2021 18:19:22

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:19:22

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:19:22

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver infiltration - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 00:10:46
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 00:10:46
Data point term sent to Coder	System	06 Mar 2021 18:22:25
User entered 'MILD FATTY INFILTRATION OF THE LIVER'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58



US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '14 Sep 2020'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:38:39
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'ongoing' (Site from DM).		29 Mar 2021 18:07:22
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		22 Mar 2021 10:00:13
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:03:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58



US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58



US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	



US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'procedure was diagnostic and not therapeutic. ' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:38:44  29 Mar 2021 18:06:37  22 Mar 2021 10:00:24
	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Mar 2021 18:21:58
	(b) (4)	

US3222388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Narrative indicates that the subject had CT of Abdomen and Pelvis. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Narrative indicates that the subject had CT of Abdomen and Pelvis. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:38:47
User opened query 'Per DM CLR: Narrative indicates that the subject had CT of Abdomen and Pelvis. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).		29 Mar 2021 18:07:04
User entered 'THIS WAS DISCOVERED BY CT OF THE ABDOMEN AND PELVIS W/C. NOT TREATED AFTER DISCOVERY.'	douglas winter (b) (4) (b) (4)	06 Mar 2021 18:21:58

US3222388

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 09 Jun 2021 16:03:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:21:58

**US3222388**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 18:21:58

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:03:07

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:16
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User closed query 'Per ETRTR: SAE "Back Surgery " page indicated medication was dosed. Please update ConMeds page accordingly, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 20:52:10
Query 'Per ETRTR: SAE "Back Surgery " page indicated medication was dosed. Please update ConMeds page accordingly, thanks.' answered with 'UPDATED CONMED PAGE' (Site from CRA).	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:43:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:05:07
User opened query 'Per ETRTR: SAE "Back Surgery " page indicated medication was dosed. Please update ConMeds page accordingly, thanks.' (Site from CRA).		09 Oct 2020 18:35:34
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:04:06

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:13:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 20:03:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 20:03:26
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 17:08:26
User entered 'GABAPENTIN'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:00
User entered 'NEUROPATHY TO FEET'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:04
User entered '600'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:06
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:12
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	douglas winter (b) (4)	05 Nov 2020 17:22:39
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:14
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:18
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:20
User entered 'UN UNK 2018'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:33:23
User entered '0'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:25
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:27
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:08:04
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 17:22:39
User entered '1'	System	09 Oct 2020 17:08:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:08:04



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 17:08:04

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:36:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:12:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:12:30
Data point term sent to Coder	System	09 Oct 2020 17:11:34
User entered 'LISINOPRIL'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:20
User entered 'HYPERTENSION'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:36:22
User entered '20'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:24
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:26
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	douglas winter (b) (4)	05 Nov 2020 17:24:14
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:31
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:33
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:38
User entered 'UN UNK 2015'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:36:41
User entered '0'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:44
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:46
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:10:39
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 17:24:14
User entered '1'	System	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:10:39

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 17:10:39

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:13:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:13:22
Data point term sent to Coder	System	09 Oct 2020 17:12:37
User entered 'OMEPRAZOLE'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	09 Oct 2020 17:11:37
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:56
User entered 'GERD'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:36:58
User entered '20'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:01
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:10
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	09 Oct 2020 17:11:37
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:06
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	09 Oct 2020 17:11:37
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:13
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:15
User entered 'UN UNK 2015'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:19
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Un-verified.	douglas winter (b) (4)	15 Nov 2020 11:00:25
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	15 Nov 2020 11:00:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:37:21
User entered 'Yes (Y)'	douglas winter (b) (4)	09 Oct 2020 17:11:37



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Un-verified.	douglas winter (b) (4)	15 Nov 2020 11:00:25
User entered '30 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	15 Nov 2020 11:00:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:37:23
User entered empty.	douglas winter (b) (4)	09 Oct 2020 17:11:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	09 Oct 2020 17:11:37
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User entered '1'	System	09 Oct 2020 17:11:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User entered '1'	System	09 Oct 2020 17:11:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:29
User entered '804 (804)'	System	09 Oct 2020 17:11:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:37:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 17:13:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 17:13:22
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 17:12:38
User entered 'ATENOLOL'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:33
User entered 'HYPERTENSION'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:37:34
User entered '10'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:37
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:37:38
User entered empty.	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:42
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:43
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:46
User entered 'UN UNK 2015'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:37:49
User entered '0'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:51
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:37:53
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	09 Oct 2020 17:12:22
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:12:22

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 17:12:22

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 11:11:53
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'PATIENT HAS A HISTORY OF GERD' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 14:10:29
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 14:38:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 11:02:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 11:02:41
Data point term sent to Coder	System	15 Nov 2020 11:01:49
User entered 'OMEPRAZOLE'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'GERD'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '40'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:01:24
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 11:01:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Nov 2020 11:01:32
User entered 'Oral (ORAL)' reason for change: Data douglas winter Entry Error	(b) (4)	15 Nov 2020 11:01:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 11:01:24
User entered empty.	douglas winter (b) (4)	15 Nov 2020 11:01:24
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:01:24

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:01:24



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Nov 2020 11:01:24

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL, PRODUCTSYNONYM: OXYCODONE/APAP [OXYCODONE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:35:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:35:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 13:03:16 07 Apr 2021 13:02:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL, PRODUCTSYNONYM: OXYCODONE/APAP [OXYCODONE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 10:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 10:52:18
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Mar 2021 17:27:53 29 Mar 2021 17:27:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL, PRODUCTSYNONYM: OXYCODONE/APAP [OXYCODONE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:26:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:26:01
Data point term sent to Coder	System	15 Nov 2020 11:03:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'OXYCODONE/APAP'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	06 Mar 2021 14:18:37
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	15 Nov 2020 11:02:50
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'LUMBAR CANAL AND FORAMINA STENOSIS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:02:48
User closed query 'Per CDM: Response noted 'LUMBAR PAIN'. Please update 'indication' as per your response. Thank you' (Site from DM).		30 Mar 2021 13:29:47
Query 'Per CDM: Response noted 'LUMBAR PAIN'. Please update 'indication' as per your response. Thank you' answered with 'corrected' (Site from DM).		29 Mar 2021 17:27:13
User entered 'lumbar pain' reason for change: Data Entry Error		29 Mar 2021 17:27:05
User opened query 'Per CDM: Response noted 'LUMBAR PAIN'. Please update 'indication' as per your response. Thank you' (Site from DM).		08 Mar 2021 11:11:03
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).		08 Mar 2021 11:11:03
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'LUMBAR PAIN' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Mar 2021 14:18:50
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:58:27
User entered 'PAIN MANAGEMENT'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '10/325'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:02:50
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:35:26
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'corrected per hospital records' (Site from DM).		07 Apr 2021 13:03:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).		07 Apr 2021 08:47:51
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:02:50

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:02:50

**Folder: Concomitant Medication and Vaccination (1)**  
**Form: Prior/Concomitant Medication and Vaccination (7)**  
**Generated On: 09 Jun 2021 16:03:07**  
[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:20:07
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'used to better control HTN' (Site from DM).		29 Mar 2021 17:45:45
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).		23 Dec 2020 14:36:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 11:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 11:05:41
Data point term sent to Coder	System	15 Nov 2020 11:04:50
User entered 'AMLODIPINE'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	15 Nov 2020 11:04:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:04:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '30 Sep 2020'	douglas winter (b) (4)	15 Nov 2020 11:04:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:35:43
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'this is a continuing medication' (Site from DM).		07 Apr 2021 13:02:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		03 Apr 2021 05:50:33
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	15 Nov 2020 11:04:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:04:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Nov 2020 11:04:43

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 14:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 14:26:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 13:02:11 07 Apr 2021 13:01:25
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 00:41:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 00:41:15
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Mar 2021 17:29:55 29 Mar 2021 17:29:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 03:24:51

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'DEXAMETHASONE'	Coder Import (b) (4) (b) (4) System douglas winter (b) (4) (b) (4)	16 Nov 2020 03:24:51  15 Nov 2020 11:14:52 15 Nov 2020 11:14:37



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	15 Nov 2020 11:14:37
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:39:25
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).		07 Apr 2021 13:01:32
User entered 'LUMBAR CANAL AND FORAMINA STENOSIS' reason for change: Data Entry Error		07 Apr 2021 13:01:25
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		07 Apr 2021 08:49:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		31 Mar 2021 08:53:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated per med records' (Site from DM).		29 Mar 2021 17:29:41
User entered 's/p laminectomy' reason for change: Data Entry Error		29 Mar 2021 17:29:30

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 14:36:54
User entered 'POSTERIOR DECOMPRESSION AT L3-S1'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '4'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '1 TABLET 3 TIMES A DAY FOR 2 DAYS. 1 TABLET TWICE A DAY FOR 2 DAYS. 1 TABLET DAILY FOR 2 DAYS.'	(b) (4) douglas winter (b) (4)	15 Nov 2020 11:14:37



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Nov 2020 11:14:47
User entered 'Oral (ORAL)' reason for change: Data douglas winter	(b) (4)	15 Nov 2020 11:14:47
Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 11:14:37
User entered empty.	douglas winter (b) (4)	15 Nov 2020 11:14:37
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	15 Nov 2020 11:14:37
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '6 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:14:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	15 Nov 2020 11:14:37
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User entered empty.	System	15 Nov 2020 11:14:37



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User entered empty.	System	15 Nov 2020 11:14:37

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:33
User entered empty.	System	15 Nov 2020 11:14:37

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:26:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 13:04:19 07 Apr 2021 13:03:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:42:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:42:17
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Mar 2021 17:30:56 29 Mar 2021 17:30:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 11:18:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 11:18:42
Data point term sent to Coder User entered 'DIAZEPAM'	System douglas winter (b) (4)	15 Nov 2020 11:17:52 15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR-RQ: Response noted. However, please note that there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:48:17
Query 'Per DM CLR-RQ: Response noted. However, please note that there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' answered with 'corrected per hospital records' (Site from DM).		07 Apr 2021 13:03:35
User entered 'LUMBAR CANAL AND FORAMINA STENOSIS' reason for change: Data Entry Error		07 Apr 2021 13:03:22
User opened query 'Per DM CLR-RQ: Response noted. However, please note that there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).		07 Apr 2021 08:50:46
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		31 Mar 2021 08:53:19
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated per medical records' (Site from DM).		29 Mar 2021 17:30:28
User entered 's/p laminectomy  MUSCLE SPASMS' reason for change: Data Entry Error		29 Mar 2021 17:30:12

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1972 of 2174

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 14:37:12
User entered 'MUSCLE SPASMS'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:17:03
	(b) (4)	



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'TID/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '27 Sep 2020'	douglas winter (b) (4)	15 Nov 2020 11:17:03
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:17:03

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:17:03

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:45:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:45:21
Data point term sent to Coder	System	29 Mar 2021 17:38:04
Data point term sent to Coder	System	29 Mar 2021 17:37:04
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 17:36:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:24:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:24:52
Data point term sent to Coder	System	15 Nov 2020 11:21:53
User entered 'DICYCLOMINE'	douglas winter (b) (4)	15 Nov 2020 11:21:43

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	15 Nov 2020 11:21:43
	(b) (4)	

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:28:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		30 Mar 2021 13:28:22
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).		29 Mar 2021 17:37:47
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).		29 Mar 2021 17:37:32
User entered 'Cholelithiasis' reason for change: Data Entry Error		29 Mar 2021 17:37:14
User entered 'Diverticulitis' reason for change: Data Entry Error		29 Mar 2021 17:36:21
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).		20 Jan 2021 10:02:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		23 Dec 2020 14:37:31



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Indication](#)

Audit	User	Time (GMT)
User entered 'CIRRHOSIS OF THE LIVER'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:21:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered '30 Sep 2020'	douglas winter (b) (4)	15 Nov 2020 11:21:43
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:21:43

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Nov 2020 11:21:43



US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL, PRODUCTSYNONYM: FENTANYL PATCH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Mar 2021 17:40:17 29 Mar 2021 17:39:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL, PRODUCTSYNONYM: FENTANYL PATCH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:24:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 03:24:52
Data point term sent to Coder	System	15 Nov 2020 11:23:54
User entered 'FENTANYL PATCH'	douglas winter (b) (4)	15 Nov 2020 11:23:38

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:48:41
Query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'corrected' (Site from DM).		07 Apr 2021 13:04:06
User entered 'No (N)' reason for change: Data Entry Error		07 Apr 2021 13:03:59
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		07 Apr 2021 08:51:37
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:18:54
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).		29 Mar 2021 17:39:41
User entered 's/p laminectomy PAIN MANAGEMENT' reason for change: Data Entry Error		29 Mar 2021 17:39:24
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).		20 Jan 2021 10:03:13
User entered 'PAIN MANAGEMENT'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '50'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:18:25
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'This dose is correct for a transdermal patch. this is directly from hospital DC records. ' (Site from DM).		29 Mar 2021 17:40:28
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).		23 Dec 2020 14:37:48
User entered 'ug (ug)'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'EVERY 3 DAYS'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:23:38



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:23:38

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 11:23:38

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Nov 2020 11:26:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 11:26:41
Data point term sent to Coder	System	15 Nov 2020 11:25:56
User entered 'MELATONIN'	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'this is not an AE. ' (Site from DM). User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM). User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:19  29 Mar 2021 17:42:28  23 Dec 2020 14:38:09
	douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '5'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	15 Nov 2020 11:25:04
	(b) (4)	

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04



US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Nov 2020 11:25:04

US3222388

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:03:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Nov 2020 11:25:04

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:03:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:16
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Un-verified.	(b) (4)	
	gail lavine (b) (4)	02 Dec 2020 15:02:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	gail lavine (b) (4)	02 Dec 2020 15:02:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:42
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Oct 2020 23:12:59
	(b) (4)	

US3222388

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:03:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '25 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 15:06:23

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:03:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered 'Laminectomy'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 15:06:23

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:34:10
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	07 Apr 2021 13:06:01
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' answered with 'procedure for LUMBAR CANAL AND FORAMINA STENOSIS' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:05:08
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	07 Apr 2021 13:05:01
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:05:01
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM).		04 Apr 2021 17:20:37
User closed query 'Per DM CLR: Please review and confirm if this was indicated for AE of Fall. If yes, Please note that, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).		30 Mar 2021 13:44:37



US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and confirm if this was indicated for AE of Fall. If yes, Please note that, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 18:11:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 18:10:55
User opened query 'Per DM CLR: Please review and confirm if this was indicated for AE of Fall. If yes, Please note that, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	04 Mar 2021 10:31:25
User entered 'Adverse Event (AE)'	gail lavine (b) (4) (b) (4)	22 Feb 2021 17:04:52
		02 Dec 2020 15:06:23

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:03:07

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:06:01
Signature has been broken.		29 Mar 2021 18:10:55
User entered 'therapeutic' reason for change: Data Entry Error		29 Mar 2021 18:10:55
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 15:06:23

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:03:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:18:26

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:03:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Ct ABD and pelvis W/C'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:18:26

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:18:26

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:03:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:18:26

US3222388

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 16:03:07**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:19:25

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:03:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Ct L spine W/O Contrast'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:19:25



US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:19:25

US3222388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:03:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:19:25

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22



**US3222388**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:03:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '09/Oct/2020 19:01'	(b) (4) System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:55:10
User entered 'I'		09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '06/Nov/2020 17:55'	(b) (4) System	06 Nov 2020 17:55:21

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:57
User entered 'I'		06 Nov 2020 17:55:21

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

**US3222388**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:03:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
User entered '16/Nov/2020 14:48'	(b) (4) System	16 Nov 2020 19:48:07

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:39:49
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 19:48:07

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

**US3222388**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:03:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '08/Mar/2021 10:39'	(b) (4) System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'I'		08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:03:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '30/Mar/2021 12:30'	(b) (4) System	30 Mar 2021 16:30:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:30:45
User entered 'I'		30 Mar 2021 16:30:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:17
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'USA-US104-2020-MRNA-1273-P301000009'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:23
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	04 Nov 2020 20:53:25
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:27
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:42
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:53:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:38
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:45
Reviewed for Safety.		09 Oct 2020 19:01:14
User entered 'No (N)'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Bruce'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Teresa'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Tracy'	System	09 Oct 2020 18:47:14

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Rankin'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
Un-reviewed for Safety.	System	08 Mar 2021 15:39:57
Signature has been broken.	System	08 Mar 2021 15:39:57
User entered 'Becker'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 19:01:14
User entered 'Kowalski'	System	09 Oct 2020 18:47:14



US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '860 Peachwood Ave'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '6550 Mapleridge Street'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered 'Deland'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered 'Houston'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:30:45
Un-reviewed for Safety.	System	30 Mar 2021 16:30:22
User entered '32720'	System	30 Mar 2021 16:30:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:29:10
User entered '77081'	System	08 Mar 2021 15:39:57

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	04 Nov 2020 20:56:49
Reviewed for Safety.		09 Oct 2020 19:01:28
User entered 'US'	System	09 Oct 2020 19:01:22

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 13:31:01
User entered '5'	System	30 Mar 2021 16:30:22
User entered '4'	System	08 Mar 2021 15:39:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 17:04:52
	(b) (4)	
User entered '3'	System	16 Nov 2020 19:48:07
User entered '2'	System	06 Nov 2020 17:55:21
User entered '1'	System	09 Oct 2020 19:01:22

**US3222388**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:03:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered '08/Apr/2021 13:30'	(b) (4) System	08 Apr 2021 13:31:01

US3222388

Folder: SAE USA-US104-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:03:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:30:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:31:01