

US3222089 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:08:08

All time stamps listed in this document are displayed in GMT

US3222089

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 15:46:45

Generated On: 09 Jun 2021 16:08:08

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[Participant ID](#)

US3222089

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

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US3222089

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

US3222089

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	MAJOR DEPRESSION
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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Condition	ANXIETY
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)	

US3222089

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:21
Height (xxx.x)	167.6 cm
Weight (xxx.x)	63.6 kg
BMI (xxx.x)	22.64170 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2014

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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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** RETIRED

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:46:46

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<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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 103143

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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)	11 AUG 2020
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:27
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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)	11 AUG 2020
Time of assessment (00:00-23:59)	17:38 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:38
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 17:07 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 17:07

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

16:35 (24 HR)

Collection date and time (derived)

11 AUG 2020 16:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:39	11 AUG 2020 16:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

11 AUG 2020 17:30

PC Open Date & Time

11 AUG 2020 17:27

PC Close Date & Time

11 AUG 2020 19:57

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**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 ☒

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

Yes ☐  
No ☒

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

PC Time Stamp	12 AUG 2020 10:34
PC Open Date & Time	11 AUG 2020 20:52
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

12 AUG 2020 20:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 20:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

15 AUG 2020 19:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**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

97.5 °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

16 AUG 2020 18:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 AUG 2020 18:21

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**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

11 AUG 2020 17:32

PC Open Date & Time

11 AUG 2020 17:27

PC Close Date & Time

11 AUG 2020 19:57

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**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

12 AUG 2020 10:31

PC Open Date & Time

11 AUG 2020 20:52

PC Close Date & Time

12 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**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

12 AUG 2020 20:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**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

13 AUG 2020 20:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**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

14 AUG 2020 18:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**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

15 AUG 2020 19:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**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

16 AUG 2020 18:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**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

17 AUG 2020 18:22

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**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 ☐

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 17:31
PC Open Date & Time	11 AUG 2020 17:27
PC Close Date & Time	11 AUG 2020 19:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**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 ☐



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 10:32
PC Open Date & Time	11 AUG 2020 20:52
PC Close Date & Time	12 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

51 of 2729

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 20:17
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**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 ☒

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:13
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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 ☒



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:38
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

57 of 2729

EAB) (1725)

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**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)

59 of 2729

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:23
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3222089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222089

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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)	12 SEP 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 13:05
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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)	12 SEP 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 14:41
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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) 12 SEP 2020

What was the treatment time? (00:00-23:59) 14:16 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 14:16

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



US3222089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 SEP 2020
Collection time (00:00-23:59)	13:50 (24 HR)
Collection date and time (derived)	12 SEP 2020 13:50

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:51	12 SEP 2020 13:51
Nasopharyngeal Swab 2	No		

US3222089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 14:36

PC Close Date & Time

12 SEP 2020 17:06

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 12 SEP 2020 18:01

PC Close Date & Time 13 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 09:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

15 SEP 2020 20:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 19:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**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

97.5 °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 SEP 2020 12:55

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**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.

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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.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 00:00

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 14:36

PC Close Date & Time

12 SEP 2020 17:06

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 18:01

PC Close Date & Time

13 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**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

14 SEP 2020 09:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**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

15 SEP 2020 20:41

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**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

16 SEP 2020 19:19

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**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

17 SEP 2020 12:55

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**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

19 SEP 2020 00:01

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**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 ☐

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 14:36

PC Close Date & Time

12 SEP 2020 17:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**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 ☐

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 18:01

PC Close Date & Time

13 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**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 ☒



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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 ☐

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2729

EAB) (1725)

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:42
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

101 of 2729

EAB) (1725)

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:21
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:56
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**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 ☒

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 00:03
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222089

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:46:53

Generated On: 09 Jun 2021 16:08:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:46:53

Generated On: 09 Jun 2021 16:08:08

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) \_\_\_\_\_

US3222089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:46:53

Generated On: 09 Jun 2021 16:08:08

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.*

US3222089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	13 OCT 2020 11:55

US3222089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59



US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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 <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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 06:37:27

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 16:51:36

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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

21 NOV 2020 15:59:02

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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	30 NOV 2020 16:11:49
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59



US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 DEC 2020 15:16:04
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 14:57:10

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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 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	17 DEC 2020 10:08:30
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 11:31:36

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 04:17:22

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 JAN 2021 20:24:45
Patient Cloud Open Date & Time	07 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
133 of 2729	

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JAN 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 12:09:13
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 JAN 2021 20:04:13
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 04:27:01
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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	22 FEB 2021 14:53:20
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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04 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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

12 MAR 2021 19:14:49

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 APR 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 06:51:16

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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26 APR 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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 <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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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 <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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 NOV 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	23 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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="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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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 <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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 768

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

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

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

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

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

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



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**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 ☐

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

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US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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"/>



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

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

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[Patient Cloud Close Date & Time](#)

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17 OCT 2022 23:59

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US3222089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:08:08

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		10 MAR 2021 20:59:26

US3222089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222089

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:40:56

Generated On: 09 Jun 2021 16:08:08

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) \_\_\_\_\_

US3222089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3222089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	15:40 (24 HR)
Collection date and time (derived)	02 MAR 2021 15:40

US3222089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222089

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3222089**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3222089**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222089

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:08:08

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"/>

**US3222089**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:08:08**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3222089

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

Form: Visit Date

Data signed: (b) (4) 02 Mar 2021 21:30:33

Generated On: 09 Jun 2021 16:08:08

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

Visit date (dd MMM yyyy)	02 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3222089

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Date of updated informed consent ( <i>dd MMM yyyy</i> )	19 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	19 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3222089

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Mar 2021 17:14:01

Generated On: 09 Jun 2021 16:08:08

Height	
Weight	
BMI (xxx.x)	



US3222089

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 17:14:01

Generated On: 09 Jun 2021 16:08:08

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 15:40
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 17:14:01

Generated On: 09 Jun 2021 16:08:08

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 16:20
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

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

Form: Physical Examination

Data signed: (b) (4) 02 Mar 2021 21:32:05

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3222089

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 02 MAR 2021

What was the treatment time? (00:00-23:59) 15:49 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 15:49

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

US3222089

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	02 MAR 2021 15:35

US3222089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00 - 23:59)	15:37
Collection Date and Time (derived)	02 MAR 2021 15:37

US3222089

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:07:35

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:14:01

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:14:01

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 APR 2021
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	09 APR 2021 14:10
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

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)	09 APR 2021
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	09 APR 2021 15:00
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3222089

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 APR 2021

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

US3222089

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 09 APR 2021

What was the treatment time? (00:00-23:59) 14:29 (24 HR)

Treatment Date and Time (derived) 09 APR 2021 14:29

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

US3222089

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222089

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3222089**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

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 \_\_\_\_\_

US3222089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

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)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 15:46:45

Generated On: 09 Jun 2021 16:08:08

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

AEID

Adverse event

SORE THROAT

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)

31 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:40:54

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	



US3222089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

AEID	USA-US104-2021-MRNA-1273-P30 1000004
Adverse event	COPD EXACERBATION
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)	23 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	27 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3222089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

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	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	I WAS INFORMED BY OUR CALL CENTER THAT THE PATIENT IS IN THE HOSPITAL. I'VE CALLED AND LEFT MESSAGES AND STILL HAVENT RECEIVED A RETURN CALL.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 26 Apr 2021 13:40:54

**Generated On: 09 Jun 2021 16:08:08**

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

AEID	USA-US104-2021-MRNA-1273-P30 1000004
Adverse event	PRIMARY SAE ACUTE DIASTOLIC HEART FAILURE
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)	23 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:40:54

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	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative	ADDING ACUTE DIASTOLIC HEART FAILURE AS A SECONDARY AE	
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)		1
Medically Attended AE Derived (CSA Programming Field Only)		1

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Data signed:** (b) (4) 26 Apr 2021 13:40:54

**Generated On: 09 Jun 2021 16:08:08**

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

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0

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

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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.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication SPRIONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication FUROSIMIDE

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication CHLORTABS

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication PENICILLIN

Prophylaxis Yes ☐  
No ☒

Indication SORE THROAT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication INFLUENZA

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration .05

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒  
No ☐

Indication FEVER OR PAIN

Dose per administration 650

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

Q4HS/PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)		24 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication ARIPIRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication MAJOR DEPRESSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☒  
No ☐

Indication COPD EXACERBATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q8HS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)		24 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication BUDESONIDE

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q12HS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication CEFTRIAZONE  
(CODEINE-GUAIFENESIN)

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

Dose per administration 10/100/5

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

If dose unit is Other, specify MG/MG/ML

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 Q4HS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)		24 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication COLACE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE  
(CONSTIPATION)

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6HS/PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication DOXEPIN

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q12HS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication FORMOTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE DIASTOLIC HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication BENZONATATE

Prophylaxis Yes ☒  
No ☐

Indication COPD EXACERBATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)		24 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication IPRATROPIUM

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

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 Q12HS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE DIASTOLIC HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 13:40:54

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Name of Medication MIRALAX

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication MULTIPLE VITAMIN WITH IRON

Prophylaxis Yes ☐  
No ☒

Indication COPD EXACERBATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication NICOTINE TRANSDERMAL FILM

Prophylaxis Yes ☐  
No ☒

Indication PREVENTATIVE

Dose per administration 14

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication ONDANSETRON

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

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

Q4HS/PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication SALINE FLUSH

Prophylaxis Yes ☐  
No ☒

Indication KEEP VAIN OPEN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication SALINE FLUSH

Prophylaxis Yes ☐  
No ☒

Indication KEEP VEIN OPEN

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

Q12HS

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

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EAB) (1725)

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 24 JAN 2021		
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"/>	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE DIASTOLIC HEART  
FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
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"/>

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication VALSARTAN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE DIASTOLIC HEART  
FAILURE

Dose per administration 320

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication MAJOR DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

Name of Medication XANAX

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 13:40:54

Generated On: 09 Jun 2021 16:08:08

	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)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3222089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 15:46:46

Generated On: 09 Jun 2021 16:08:08

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3222089

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:08:08

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

US3222089

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:08:08

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 ☐

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	26/JAN/2021 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:46
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

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 12:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 13:40:55

Generated On: 09 Jun 2021 16:08:08

SAEID	USA-US104-2021-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	21/APR/2021 13:47
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

US3222089 (Prod: Accel Research Site - Avail - ERN-PPDS)

**US3222089**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:08:08**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US3222089'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:24:53

US3222089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:37

US3222089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:24:54



US3222089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:37

**US3222089**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'SCRN'	System	11 Aug 2020 19:28:37

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered (b) (6) 1947' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:19:24
User entered 'SEP 1988'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:24:55

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
Query 'Age does not fit Cohort. Please review and update.' canceled (Site from DM).	(b) (4)	17 Apr 2021 17:12:19
User opened query 'Age does not fit Cohort. Please review and update.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:24:20
Query 'Age does not fit Cohort. Please review and update.' canceled (Site from System).	(b) (4), (b) (6)	12 Apr 2021 13:24:09
Comment added 'Unable to answer this query.'.	Jennifer Dittman (b) (4)	09 Apr 2021 18:20:58
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	(b) (4)	08 Apr 2021 17:26:24
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	08 Apr 2021 17:26:24
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	08 Apr 2021 17:26:24
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:26:24
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	08 Apr 2021 17:26:13
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	08 Apr 2021 17:26:13
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	08 Apr 2021 17:26:13
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:26:13
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 21:34:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 21:34:48
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	09 Mar 2021 21:34:48
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	09 Mar 2021 21:34:48
User entered '72' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	09 Mar 2021 21:34:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Mar 2021 21:34:26
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	09 Mar 2021 21:34:26

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

Age

Audit	User	Time (GMT)
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	09 Mar 2021 21:34:26
User entered empty; reason for change Data Entry Error	Jennifer Dittman (b) (4)	09 Mar 2021 21:34:26
Comment added 'Deviations already noted, please remove query.'	Thais Truffa (b) (4)	13 Feb 2021 12:37:19
Comment added 'DCR HAS BEEN SUBMITTED TO CHANGE COHORT.'	Albert Garcia (b) (4)	15 Sep 2020 21:54:17
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Sep 2020 17:36:55
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Sep 2020 17:36:55
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	10 Sep 2020 17:36:55
User entered '72' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	10 Sep 2020 17:36:55
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Sep 2020 17:36:06
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	10 Sep 2020 17:36:06
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Sep 2020 17:36:06
User entered '73' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	10 Sep 2020 17:36:06
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	12 Aug 2020 14:19:24
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	11 Aug 2020 21:49:23
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	11 Aug 2020 21:49:23
User entered '72'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'YEARS'	System	09 Mar 2021 21:34:48
User entered empty.	System	09 Mar 2021 21:34:26
User entered 'YEARS'	System	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '72'	System	12 Aug 2020 14:19:24
User entered '31'	System	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:27:41
Query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' answered with 'DATA IS ENTERED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	06 Sep 2020 15:19:05
User opened query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:23:09
User entered 'Female (F)'	Crystal Paccione (b) (4) (b) (4)	11 Aug 2020 21:49:23



US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'I'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23



US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	Crystal Paccione (b) (4)	11 Aug 2020 21:49:23

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Aug 2020'	System	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2020'	System	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56



US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:28:56

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:24:54

US3222089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'I'	System	11 Aug 2020 19:29:01

US3222089

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:29:01

US3222089

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:08:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:06:53

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:08:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:08:58
Data point term sent to Coder	System	06 Sep 2020 15:07:57
User entered 'COPD'	Albert Garcia (b) (4)	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'un UNK 2014'	Albert Garcia (b) (4)	06 Sep 2020 15:07:52



US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 2014'	System	06 Sep 2020 15:07:52

**US3222089**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2014'	System	06 Sep 2020 15:07:52

US3222089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:07:52

**US3222089**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:07:52



US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:01
Data point term sent to Coder	System	06 Sep 2020 15:08:57
User entered 'Hypertension'	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '01 Jan 1995'	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

**US3222089**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 1995'	System	06 Sep 2020 15:08:25

**US3222089**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '1995'	System	06 Sep 2020 15:08:25



US3222089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:08:25

**US3222089**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:08:25

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:47
Data point term sent to Coder	System	06 Sep 2020 15:09:58
User entered 'Hysterectomy'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'un UNK 2002'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'un UNK 2002'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:08:59



US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 2002'	System	06 Sep 2020 15:08:59

**US3222089**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2002'	System	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 2002'	System	06 Sep 2020 15:08:59

**US3222089**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2002'	System	06 Sep 2020 15:08:59

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:10:47
Data point term sent to Coder	System	06 Sep 2020 15:09:58
User entered 'Postmenopausal'	Albert Garcia (b) (4)	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Please note, Start date of MH = UNK 2004 However, Post-menopausal date recorded in Childbearing eCRF is UNK 2014. Review if this should be reconciled. Else, Please clarify dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:38:50
Query 'Per DM CLR: Please note, Start date of MH = UNK 2004 However, Post-menopausal date recorded in Childbearing eCRF is UNK 2014. Review if this should be reconciled. Else, Please clarify dates. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:11:50
User entered 'UN UNK 2014' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:11:43
User opened query 'Per DM CLR: Please note, Start date of MH = UNK 2004 However, Post-menopausal date recorded in Childbearing eCRF is UNK 2014. Review if this should be reconciled. Else, Please clarify dates. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:49:35
User entered 'un UNK 2004'	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:09:18



US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 2014'	System	12 Oct 2020 17:11:43
User entered 'Jan 2004'	System	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2014'	System	12 Oct 2020 17:11:43
User entered '2004'	System	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:09:18

**US3222089**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	06 Sep 2020 15:09:18

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 18:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 18:35:34
Data point term sent to Coder	System	09 Nov 2020 18:35:19
User entered 'SEASONAL ALLERGIES'	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'UN UNK 2001'	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14



US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14

**US3222089**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:08:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Alicia Cevera (b) (4)	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'Jan 2001'	System	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '2001'	System	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	09 Nov 2020 18:35:14

US3222089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	09 Nov 2020 18:35:14



US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Major depression - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 20:54:36
Data point term sent to Coder	System	20 Apr 2021 20:53:13
User entered 'MAJOR DEPRESSION'	douglas winter (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	20 Apr 2021 20:52:51

**US3222089**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	20 Apr 2021 20:52:51



US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	20 Apr 2021 20:52:51

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 15:15:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 15:15:23
Data point term sent to Coder	System	21 Apr 2021 14:51:47
User entered 'ANXIETY'	douglas winter (b) (4)	21 Apr 2021 14:51:33
	(b) (4)	

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:51:33



US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	21 Apr 2021 14:51:33

**US3222089**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	21 Apr 2021 14:51:33

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16:21'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '11 Aug 2020 16:21'	System	06 Sep 2020 15:10:41



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '167.6' cm	(b) (4) Albert Garcia (b) (4)	06 Sep 2020 15:10:41
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:29:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '63.6' kg	Albert Garcia (b) (4)	06 Sep 2020 15:10:41
DataPoint set to visible.	System	11 Aug 2020 19:29:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '22.64170'	System	06 Sep 2020 15:10:41
DataPoint set to visible.	System	11 Aug 2020 19:29:01

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'kg/m2'	System	06 Sep 2020 15:10:41
DataPoint set to visible.	System	11 Aug 2020 19:29:01

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
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)	21 Sep 2020 15:43:01
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)	15 Sep 2020 21:53:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:53:11
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 13:18:39
User entered '36.7' C	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:10:41

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	15 Sep 2020 21:53:11
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:10:41

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:53:11
User entered '62'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41
	(b) (4)	



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Folder: Screening

Form: Vital Signs

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'bpm'	System	06 Sep 2020 15:10:41

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:53:11
User entered '16'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'breaths/min'	System	06 Sep 2020 15:10:41

US3222089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:53:11
User entered '122'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'mmHg'	System	06 Sep 2020 15:10:41

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:53:11
User entered '72'	Albert Garcia (b) (4)	06 Sep 2020 15:10:41
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'mmHg'	System	06 Sep 2020 15:10:41

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28

US3222089

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:10:49

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	18 Sep 2020 18:48:37
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:48:37
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:48:37
User entered '11 Aug 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:48:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:48:33
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:48:33
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	18 Sep 2020 18:48:33
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:48:33
User entered '11 Feb 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:48:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:21:33
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:10:49
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

US3222089

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:12:00



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Folder: Screening

Form: Childbearing Potential

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Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:08

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'un UNK 2014' reason for change: Data Entry Error	System	06 Sep 2020 15:12:20
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	Albert Garcia (b) (4)	06 Sep 2020 15:12:20
User entered empty.	(b) (4)	
	System	06 Sep 2020 15:12:00
	Albert Garcia (b) (4)	06 Sep 2020 15:12:00
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

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Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Albert Garcia (b) (4)	06 Sep 2020 15:12:00

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Folder: Screening

Form: Risk of Exposure

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**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24



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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'RETIRED'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24



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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'I'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24

US3222089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	11 Aug 2020 21:15:24



US3222089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:29:20

US3222089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Jennifer Dittman (b) (4)	11 Aug 2020 19:29:20

US3222089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	11 Aug 2020 19:29:20

**US3222089**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'VISIT1'	System	11 Aug 2020 19:29:20

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:44:22

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:39:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:39:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 20:44:22
User entered '103143' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:44:22

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Subject with +Chronic Lung Disease; please enter PD as subject should have been at risk strata' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:22:21
Query 'Subject with +Chronic Lung Disease; please enter PD as subject should have been at risk strata' answered with 'A PD WILL BE COMPLETED AND SOTED IN THE SUBJECT CHART.' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	16 Nov 2020 18:55:59
User opened query 'Subject with +Chronic Lung Disease; please enter PD as subject should have been at risk strata' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:43:05
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:44:22

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:16:46



US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:16:46

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:16:46

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:16:46

US3222089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:16:46

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:34
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:37
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:41
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:34
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:37
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:41
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16:27'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '11 Aug 2020 16:27'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '36.7' C	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:14:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '60'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'bpm'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '14'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'breaths/min'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '116'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '70'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	06 Sep 2020 15:14:08



US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:34
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:37
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:43:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:20:50
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:20:41
User entered empty.	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '17:38'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '11 Aug 2020 17:38'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '36.7' C	Albert Garcia (b) (4)	06 Sep 2020 15:14:08



US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '60'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'bpm'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'breaths/min'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '118'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	06 Sep 2020 15:14:08



US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '70'	Albert Garcia (b) (4)	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	06 Sep 2020 15:14:08

US3222089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	06 Sep 2020 15:14:20

US3222089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:20

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 21:17:14



US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '17:07'	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '11 Aug 2020 17:07'	System	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'ONCE'	System	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 21:17:14

US3222089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:14:45

US3222089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:14:45



US3222089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16:35'	Albert Garcia (b) (4)	06 Sep 2020 15:14:45

US3222089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '11 Aug 2020 16:35'	System	06 Sep 2020 15:14:45

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:08:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Aug 2020'	Albert Garcia (b) (4)	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16:39'	Albert Garcia (b) (4)	06 Sep 2020 15:15:02

**US3222089**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered '11 Aug 2020 16:39'	System	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:15:02



US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered empty.	System	06 Sep 2020 15:15:02

US3222089

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Sep 2020 15:15:07

**US3222089**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	06 Sep 2020 15:15:07

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:30:11', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd2040f7e-a2dc-4fe7-887e-330e42138538'	System	11 Aug 2020 21:30:46
User entered 'Yes (Y)'	System	11 Aug 2020 21:30:46

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:30:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd2040f7e-a2dc-4fe7-887e-330e42138538'	System	11 Aug 2020 21:30:46
User entered '97.5'	System	11 Aug 2020 21:30:46



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:30:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd2040f7e-a2dc-4fe7-887e-330e42138538'	System	11 Aug 2020 21:30:46
User entered 'No (N)'	System	11 Aug 2020 21:30:46

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:30:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd2040f7e-a2dc-4fe7-887e-330e42138538'	System	11 Aug 2020 21:30:46
User entered '11 Aug 2020 17:30'	System	11 Aug 2020 21:30:46

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 17:27'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 19:57'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:34:27', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f3302c46-e652-4c36-b8d1-e1001b624c04'	System	12 Aug 2020 14:34:44
User entered 'No (N)'	System	12 Aug 2020 14:34:44

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:34:34', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f3302c46-e652-4c36-b8d1-e1001b624c04'	System	12 Aug 2020 14:34:44
User entered 'No (N)'	System	12 Aug 2020 14:34:44

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:34:42', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f3302c46-e652-4c36-b8d1-e1001b624c04'	System	12 Aug 2020 14:34:44
User entered '12 Aug 2020 10:34'	System	12 Aug 2020 14:34:44



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 20:52'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 2'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:16:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd24cbf5f-54a9-4019-8fd2-d743e7a43fe6'	System	13 Aug 2020 00:16:58
User entered 'Yes (Y)'	System	13 Aug 2020 00:16:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:16:40', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd24cbf5f-54a9-4019-8fd2-d743e7a43fe6'	System	13 Aug 2020 00:16:58
User entered '97.5'	System	13 Aug 2020 00:16:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:16:45', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd24cbf5f-54a9-4019-8fd2-d743e7a43fe6'	System	13 Aug 2020 00:16:58
User entered 'No (N)'	System	13 Aug 2020 00:16:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:16:55', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd24cbf5f-54a9-4019-8fd2-d743e7a43fe6'	System	13 Aug 2020 00:16:58
User entered '12 Aug 2020 20:16'	System	13 Aug 2020 00:16:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 3'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:15:54', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0f2c17d3-227e-4358-9271-0fc62d6e48a0'	System	14 Aug 2020 00:16:19
User entered 'Yes (Y)'	System	14 Aug 2020 00:16:19

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0f2c17d3-227e-4358-9271-0fc62d6e48a0'	System	14 Aug 2020 00:16:19
User entered '97.3'	System	14 Aug 2020 00:16:19

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:11', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0f2c17d3-227e-4358-9271-0fc62d6e48a0'	System	14 Aug 2020 00:16:19
User entered 'No (N)'	System	14 Aug 2020 00:16:19

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:17', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0f2c17d3-227e-4358-9271-0fc62d6e48a0'	System	14 Aug 2020 00:16:19
User entered '13 Aug 2020 20:16'	System	14 Aug 2020 00:16:19

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 4'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:11:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '43af2509-e098-4ef9-b372-4b1420cb2a4f'	System	14 Aug 2020 22:11:58
User entered 'Yes (Y)'	System	14 Aug 2020 22:11:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:11:40', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '43af2509-e098-4ef9-b372-4b1420cb2a4f'	System	14 Aug 2020 22:11:58
User entered '97.8'	System	14 Aug 2020 22:11:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:11:48', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '43af2509-e098-4ef9-b372-4b1420cb2a4f'	System	14 Aug 2020 22:11:58
User entered 'No (N)'	System	14 Aug 2020 22:11:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:11:55', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '43af2509-e098-4ef9-b372-4b1420cb2a4f'	System	14 Aug 2020 22:11:58
User entered '14 Aug 2020 18:11'	System	14 Aug 2020 22:11:58

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 5'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:36:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '412f657f-00d4-473b-a382-0b06db857175'	System	15 Aug 2020 23:37:11
User entered 'Yes (Y)'	System	15 Aug 2020 23:37:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:36:55', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '412f657f-00d4-473b-a382-0b06db857175'	System	15 Aug 2020 23:37:11
User entered '97.3'	System	15 Aug 2020 23:37:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '412f657f-00d4-473b-a382-0b06db857175'	System	15 Aug 2020 23:37:11
User entered 'No (N)'	System	15 Aug 2020 23:37:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '412f657f-00d4-473b-a382-0b06db857175'	System	15 Aug 2020 23:37:11
User entered '15 Aug 2020 19:37'	System	15 Aug 2020 23:37:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 6'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:05:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a8215b4c-3041-4849-bfca-a10c9c9201f1'	System	16 Aug 2020 22:06:11
User entered 'Yes (Y)'	System	16 Aug 2020 22:06:11



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:05:56', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a8215b4c-3041-4849-bfca-a10c9c9201f1'	System	16 Aug 2020 22:06:11
User entered '97.5'	System	16 Aug 2020 22:06:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a8215b4c-3041-4849-bfca-a10c9c9201f1'	System	16 Aug 2020 22:06:11
User entered 'No (N)'	System	16 Aug 2020 22:06:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a8215b4c-3041-4849-bfca-a10c9c9201f1'	System	16 Aug 2020 22:06:11
User entered '16 Aug 2020 18:06'	System	16 Aug 2020 22:06:11

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 7'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:20:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'dce5cf1a-c219-483a-bfe8-bcc6752e514e'	System	17 Aug 2020 22:21:16
User entered 'Yes (Y)'	System	17 Aug 2020 22:21:16

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:20:59', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'dce5cf1a-c219-483a-bfe8-bcc6752e514e'	System	17 Aug 2020 22:21:16
User entered '97.5'	System	17 Aug 2020 22:21:16



US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:21:06', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'dce5cf1a-c219-483a-bfe8-bcc6752e514e'	System	17 Aug 2020 22:21:16
User entered 'No (N)'	System	17 Aug 2020 22:21:16

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:21:12', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'dce5cf1a-c219-483a-bfe8-bcc6752e514e'	System	17 Aug 2020 22:21:16
User entered '17 Aug 2020 18:21'	System	17 Aug 2020 22:21:16

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:56', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93488525-17fe-4dd3-b1a3-44a9fb9e8567'	System	11 Aug 2020 21:32:34
User entered 'None (1)'	System	11 Aug 2020 21:32:34

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:32:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93488525-17fe-4dd3-b1a3-44a9fb9e8567'	System	11 Aug 2020 21:32:34
User entered 'No (N)'	System	11 Aug 2020 21:32:34

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:32:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93488525-17fe-4dd3-b1a3-44a9fb9e8567'	System	11 Aug 2020 21:32:34
User entered 'No (N)'	System	11 Aug 2020 21:32:34



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:32:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93488525-17fe-4dd3-b1a3-44a9fb9e8567'	System	11 Aug 2020 21:32:34
User entered 'None (1)'	System	11 Aug 2020 21:32:34

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:32:27', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93488525-17fe-4dd3-b1a3-44a9fb9e8567'	System	11 Aug 2020 21:32:34
User entered '11 Aug 2020 17:32'	System	11 Aug 2020 21:32:34

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 17:27'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 19:57'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:31:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1026cb06-6627-45f1-afe0-65b7a37fec2f'	System	12 Aug 2020 14:31:53
User entered 'None (1)'	System	12 Aug 2020 14:31:53

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:31:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1026cb06-6627-45f1-afe0-65b7a37fec2f'	System	12 Aug 2020 14:31:53
User entered 'No (N)'	System	12 Aug 2020 14:31:53

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:31:19', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1026cb06-6627-45f1-afe0-65b7a37fec2f'	System	12 Aug 2020 14:31:53
User entered 'No (N)'	System	12 Aug 2020 14:31:53



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:31:31', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1026cb06-6627-45f1-afe0-65b7a37fec2f'	System	12 Aug 2020 14:31:53
User entered 'None (1)'	System	12 Aug 2020 14:31:53

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:31:51', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1026cb06-6627-45f1-afe0-65b7a37fec2f'	System	12 Aug 2020 14:31:53
User entered '12 Aug 2020 10:31'	System	12 Aug 2020 14:31:53

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 20:52'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 2'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f793d0da-6e97-482f-bc65-eede96e0c86f'	System	13 Aug 2020 00:17:22
User entered 'None (1)'	System	13 Aug 2020 00:17:22

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f793d0da-6e97-482f-bc65-eede96e0c86f'	System	13 Aug 2020 00:17:22
User entered 'No (N)'	System	13 Aug 2020 00:17:22

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:11', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f793d0da-6e97-482f-bc65-eede96e0c86f'	System	13 Aug 2020 00:17:22
User entered 'No (N)'	System	13 Aug 2020 00:17:22



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:15', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f793d0da-6e97-482f-bc65-eede96e0c86f'	System	13 Aug 2020 00:17:22
User entered 'None (1)'	System	13 Aug 2020 00:17:22

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'f793d0da-6e97-482f-bc65-eede96e0c86f'	System	13 Aug 2020 00:17:22
User entered '12 Aug 2020 20:17'	System	13 Aug 2020 00:17:22

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 3'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '21ffa42a-58e3-4554-9537-3219eb856b24'	System	14 Aug 2020 00:16:50
User entered 'None (1)'	System	14 Aug 2020 00:16:50

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '21ffa42a-58e3-4554-9537-3219eb856b24'	System	14 Aug 2020 00:16:50
User entered 'No (N)'	System	14 Aug 2020 00:16:50

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:36', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '21ffa42a-58e3-4554-9537-3219eb856b24'	System	14 Aug 2020 00:16:50
User entered 'No (N)'	System	14 Aug 2020 00:16:50



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '21ffa42a-58e3-4554-9537-3219eb856b24'	System	14 Aug 2020 00:16:50
User entered 'None (1)'	System	14 Aug 2020 00:16:50

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '21ffa42a-58e3-4554-9537-3219eb856b24'	System	14 Aug 2020 00:16:50
User entered '13 Aug 2020 20:16'	System	14 Aug 2020 00:16:50

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 4'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cefa2290-43d8-46b9-83d3-2db4ba48c17a'	System	14 Aug 2020 22:12:25
User entered 'None (1)'	System	14 Aug 2020 22:12:25

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cefa2290-43d8-46b9-83d3-2db4ba48c17a'	System	14 Aug 2020 22:12:25
User entered 'No (N)'	System	14 Aug 2020 22:12:25

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cefa2290-43d8-46b9-83d3-2db4ba48c17a'	System	14 Aug 2020 22:12:25
User entered 'No (N)'	System	14 Aug 2020 22:12:25



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:15', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cefa2290-43d8-46b9-83d3-2db4ba48c17a'	System	14 Aug 2020 22:12:25
User entered 'None (1)'	System	14 Aug 2020 22:12:25

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:22', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cefa2290-43d8-46b9-83d3-2db4ba48c17a'	System	14 Aug 2020 22:12:25
User entered '14 Aug 2020 18:12'	System	14 Aug 2020 22:12:25

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 5'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:14', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '3ba75eef-eaa2-4747-b275-a13d1ed84f45'	System	15 Aug 2020 23:37:37
User entered 'None (1)'	System	15 Aug 2020 23:37:37

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:19', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '3ba75eef-eaa2-4747-b275-a13d1ed84f45'	System	15 Aug 2020 23:37:37
User entered 'No (N)'	System	15 Aug 2020 23:37:37

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '3ba75eef-eaa2-4747-b275-a13d1ed84f45'	System	15 Aug 2020 23:37:37
User entered 'No (N)'	System	15 Aug 2020 23:37:37



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '3ba75eef-eaa2-4747-b275-a13d1ed84f45'	System	15 Aug 2020 23:37:37
User entered 'None (1)'	System	15 Aug 2020 23:37:37

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:31', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '3ba75eef-eea2-4747-b275-a13d1ed84f45'	System	15 Aug 2020 23:37:37
User entered '15 Aug 2020 19:37'	System	15 Aug 2020 23:37:37

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 6'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:18', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '14a5958d-54de-4ca9-b1d7-4d09d12461a8'	System	16 Aug 2020 22:06:42
User entered 'None (1)'	System	16 Aug 2020 22:06:42

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '14a5958d-54de-4ca9-b1d7-4d09d12461a8'	System	16 Aug 2020 22:06:42
User entered 'No (N)'	System	16 Aug 2020 22:06:42

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '14a5958d-54de-4ca9-b1d7-4d09d12461a8'	System	16 Aug 2020 22:06:42
User entered 'No (N)'	System	16 Aug 2020 22:06:42



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:34', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '14a5958d-54de-4ca9-b1d7-4d09d12461a8'	System	16 Aug 2020 22:06:42
User entered 'None (1)'	System	16 Aug 2020 22:06:42

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '14a5958d-54de-4ca9-b1d7-4d09d12461a8'	System	16 Aug 2020 22:06:42
User entered '16 Aug 2020 18:06'	System	16 Aug 2020 22:06:42

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 7'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:21:31', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7dd45b5f-7899-43e3-9bf9-e4f532263516'	System	17 Aug 2020 22:22:11
User entered 'None (1)'	System	17 Aug 2020 22:22:11

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:21:36', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7dd45b5f-7899-43e3-9bf9-e4f532263516'	System	17 Aug 2020 22:22:11
User entered 'No (N)'	System	17 Aug 2020 22:22:11

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:21:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7dd45b5f-7899-43e3-9bf9-e4f532263516'	System	17 Aug 2020 22:22:11
User entered 'No (N)'	System	17 Aug 2020 22:22:11



US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7dd45b5f-7899-43e3-9bf9-e4f532263516'	System	17 Aug 2020 22:22:11
User entered 'None (1)'	System	17 Aug 2020 22:22:11

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:08', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7dd45b5f-7899-43e3-9bf9-e4f532263516'	System	17 Aug 2020 22:22:11
User entered '17 Aug 2020 18:22'	System	17 Aug 2020 22:22:11

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:04', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:09', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:17', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:21', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:25', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'None (0)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:32', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered 'No (N)'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-11T17:31:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6938d1a8-aa08-47f7-b256-d584432095db'	System	11 Aug 2020 21:31:45
User entered '11 Aug 2020 17:31'	System	11 Aug 2020 21:31:45

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 17:27'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 19:57'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:04', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:14', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:26', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:31', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'None (0)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered 'No (N)'	System	12 Aug 2020 14:32:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T10:32:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '39525215-4242-415a-9355-ba9a9a585b99'	System	12 Aug 2020 14:32:57
User entered '12 Aug 2020 10:32'	System	12 Aug 2020 14:32:57



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '11 Aug 2020 20:52'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 2'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:26', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:34', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:45', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:50', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:17:54', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'None (0)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:18:01', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered 'No (N)'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-12T20:18:08', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'a9722df3-17d3-4fd2-adbe-a61eb578184a'	System	13 Aug 2020 00:18:10
User entered '12 Aug 2020 20:18'	System	13 Aug 2020 00:18:10

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 3'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:56', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:16:59', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:06', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:24', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'None (0)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered 'No (N)'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-13T20:17:51', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '78d7076f-fd2a-48ec-8f4a-a933998c4dab'	System	14 Aug 2020 00:17:57
User entered '13 Aug 2020 20:17'	System	14 Aug 2020 00:17:57

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 4'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:42', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:12:49', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'None (0)'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:13:01', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered 'No (N)'	System	14 Aug 2020 22:13:12



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-14T18:13:06', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'c1b68eb2-e7b5-4e9b-bc12-b6ca9820f369'	System	14 Aug 2020 22:13:12
User entered '14 Aug 2020 18:13'	System	14 Aug 2020 22:13:12

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 5'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:45', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:50', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:37:57', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'None (0)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:38:06', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered 'No (N)'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-15T19:38:11', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6ad13241-eb2d-4be8-84db-43cfe53f8b41'	System	15 Aug 2020 23:38:14
User entered '15 Aug 2020 19:38'	System	15 Aug 2020 23:38:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 6'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:49', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:06:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:05', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'None (0)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:17', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered 'No (N)'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-16T18:07:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '93b3f90f-017f-4e12-b241-11cd390a9eca'	System	16 Aug 2020 22:07:33
User entered '16 Aug 2020 18:07'	System	16 Aug 2020 22:07:33

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 21:17:14



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 7'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:22', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:38', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:44', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:22:59', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'None (0)'	System	17 Aug 2020 22:23:20



US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:23:09', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered 'No (N)'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-08-17T18:23:15', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '9d95f03c-f79f-42b4-8f61-fe10aa6f8006'	System	17 Aug 2020 22:23:20
User entered '17 Aug 2020 18:23'	System	17 Aug 2020 22:23:20

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 21:17:14

US3222089

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:04

US3222089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '18 Aug 2020'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:04

US3222089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:04

US3222089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:04



US3222089

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:09

**US3222089**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	10 Sep 2020 17:41:09

US3222089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:30

US3222089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '26 Aug 2020'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:30

US3222089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:30

US3222089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:30

US3222089

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:41:36

**US3222089**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	10 Sep 2020 17:41:36



US3222089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:42:13

US3222089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '03 Sep 2020'	Jennifer Dittman (b) (4)	10 Sep 2020 17:42:13

US3222089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:42:13

US3222089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	10 Sep 2020 17:42:13

US3222089

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Sep 2020 17:42:19

**US3222089**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	10 Sep 2020 17:42:19

US3222089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:21:33

US3222089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:21:33



US3222089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Clinic (Clinic)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:21:33

US3222089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'VISIT2'	System	14 Sep 2020 13:21:33

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '13:05'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '12 Sep 2020 13:05'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '36.4' C	Amber Vasquez (b) (4)	14 Sep 2020 13:22:53



US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '78'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'bpm'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'breaths/min'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '136'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	14 Sep 2020 13:22:53



US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '90'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '14:41'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '12 Sep 2020 14:41'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '36.2' C	Amber Vasquez (b) (4)	14 Sep 2020 13:22:53



US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '81'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'bpm'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '16'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'breaths/min'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '142'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	14 Sep 2020 13:22:53



US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '86'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'mmHg'	System	14 Sep 2020 13:22:53

US3222089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:23:02

US3222089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:23:02

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 18:55:09



US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '14:16'	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '12 Sep 2020 14:16'	System	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'ONCE'	System	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 18:55:09

US3222089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:23:21

US3222089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:21



US3222089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '13:50'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:21

US3222089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '12 Sep 2020 13:50'	System	14 Sep 2020 13:23:21

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '12 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '13:51'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '12 Sep 2020 13:51'	System	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:37



US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:23:37

**US3222089**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Sep 2020 13:23:37

US3222089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	14 Sep 2020 13:07:18

**US3222089**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'I'	System	14 Sep 2020 13:07:18

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 14:36'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 17:06'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 18:01'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 2'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:09:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '394cd8ef-b4cb-4930-9e46-868561a6fa7b'	System	14 Sep 2020 13:11:16
User entered 'Yes (Y)'	System	14 Sep 2020 13:11:16

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:10:55', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '394cd8ef-b4cb-4930-9e46-868561a6fa7b'	System	14 Sep 2020 13:11:16
User entered '97.7'	System	14 Sep 2020 13:11:16

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:11:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '394cd8ef-b4cb-4930-9e46-868561a6fa7b'	System	14 Sep 2020 13:11:16
User entered 'No (N)'	System	14 Sep 2020 13:11:16

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:11:12', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '394cd8ef-b4cb-4930-9e46-868561a6fa7b'	System	14 Sep 2020 13:11:16
User entered '14 Sep 2020 09:11'	System	14 Sep 2020 13:11:16

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 3'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 4'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:12', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7d8811d3-0369-43cf-ae44-191bf0140c07'	System	16 Sep 2020 00:40:38
User entered 'Yes (Y)'	System	16 Sep 2020 00:40:38

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:22', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7d8811d3-0369-43cf-ae44-191bf0140c07'	System	16 Sep 2020 00:40:38
User entered '97.5'	System	16 Sep 2020 00:40:38

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7d8811d3-0369-43cf-ae44-191bf0140c07'	System	16 Sep 2020 00:40:38
User entered 'No (N)'	System	16 Sep 2020 00:40:38

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:35', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7d8811d3-0369-43cf-ae44-191bf0140c07'	System	16 Sep 2020 00:40:38
User entered '15 Sep 2020 20:40'	System	16 Sep 2020 00:40:38

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 5'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:17:57', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'faa66945-37a3-42a2-a271-f6e9ce7c1d1d'	System	16 Sep 2020 23:18:44
User entered 'Yes (Y)'	System	16 Sep 2020 23:18:44



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:18:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'faa66945-37a3-42a2-a271-f6e9ce7c1d1d'	System	16 Sep 2020 23:18:44
User entered '97.6'	System	16 Sep 2020 23:18:44

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:18:34', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'faa66945-37a3-42a2-a271-f6e9ce7c1d1d'	System	16 Sep 2020 23:18:44
User entered 'No (N)'	System	16 Sep 2020 23:18:44

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:18:42', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'faa66945-37a3-42a2-a271-f6e9ce7c1d1d'	System	16 Sep 2020 23:18:44
User entered '16 Sep 2020 19:18'	System	16 Sep 2020 23:18:44

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 6'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:54:54', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '19275277-b84a-4d16-90fa-9999bc5bd6fd'	System	17 Sep 2020 16:55:20
User entered 'Yes (Y)'	System	17 Sep 2020 16:55:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '19275277-b84a-4d16-90fa-9999bc5bd6fd' User entered '97.5'	System	17 Sep 2020 16:55:20
	System	17 Sep 2020 16:55:20



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:08', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '19275277-b84a-4d16-90fa-9999bc5bd6fd'	System	17 Sep 2020 16:55:20
User entered 'No (N)'	System	17 Sep 2020 16:55:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:15', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '19275277-b84a-4d16-90fa-9999bc5bd6fd'	System	17 Sep 2020 16:55:20
User entered '17 Sep 2020 12:55'	System	17 Sep 2020 16:55:20

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 7'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:00:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0c672bc9-513d-475a-ab50-eb58f3264e91'	System	19 Sep 2020 04:03:40
User entered 'Yes (Y)'	System	19 Sep 2020 04:03:40

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:00:27', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0c672bc9-513d-475a-ab50-eb58f3264e91'	System	19 Sep 2020 04:03:40
User entered '97.6'	System	19 Sep 2020 04:03:40

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:00:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0c672bc9-513d-475a-ab50-eb58f3264e91'	System	19 Sep 2020 04:03:40
User entered 'No (N)'	System	19 Sep 2020 04:03:40



US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:00:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0c672bc9-513d-475a-ab50-eb58f3264e91'	System	19 Sep 2020 04:03:40
User entered '19 Sep 2020 00:00'	System	19 Sep 2020 04:03:40

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 14:36'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 17:06'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 18:01'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 2'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '71f5092f-51ed-48a6-ad5b-f58e39f6bf5a'	System	14 Sep 2020 13:12:40
User entered 'None (1)'	System	14 Sep 2020 13:12:40

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:09', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '71f5092f-51ed-48a6-ad5b-f58e39f6bf5a'	System	14 Sep 2020 13:12:40
User entered 'No (N)'	System	14 Sep 2020 13:12:40

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '71f5092f-51ed-48a6-ad5b-f58e39f6bf5a'	System	14 Sep 2020 13:12:40
User entered 'No (N)'	System	14 Sep 2020 13:12:40

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:21', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '71f5092f-51ed-48a6-ad5b-f58e39f6bf5a'	System	14 Sep 2020 13:12:40
User entered 'None (1)'	System	14 Sep 2020 13:12:40

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '71f5092f-51ed-48a6-ad5b-f58e39f6bf5a'	System	14 Sep 2020 13:12:40
User entered '14 Sep 2020 09:12'	System	14 Sep 2020 13:12:40

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 3'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 4'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:43', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'e80e3837-2118-41b6-8496-929245eb04d2'	System	16 Sep 2020 00:41:07
User entered 'None (1)'	System	16 Sep 2020 00:41:07

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'e80e3837-2118-41b6-8496-929245eb04d2'	System	16 Sep 2020 00:41:07
User entered 'No (N)'	System	16 Sep 2020 00:41:07

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:51', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'e80e3837-2118-41b6-8496-929245eb04d2'	System	16 Sep 2020 00:41:07
User entered 'No (N)'	System	16 Sep 2020 00:41:07

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:40:55', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'e80e3837-2118-41b6-8496-929245eb04d2'	System	16 Sep 2020 00:41:07
User entered 'None (1)'	System	16 Sep 2020 00:41:07

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'e80e3837-2118-41b6-8496-929245eb04d2'	System	16 Sep 2020 00:41:07
User entered '15 Sep 2020 20:41'	System	16 Sep 2020 00:41:07

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 5'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:18:54', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '36ff991b-31ca-4669-a072-ed1b6eca45a2'	System	16 Sep 2020 23:20:02
User entered 'None (1)'	System	16 Sep 2020 23:20:02

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:18:59', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '36ff991b-31ca-4669-a072-ed1b6eca45a2'	System	16 Sep 2020 23:20:02
User entered 'No (N)'	System	16 Sep 2020 23:20:02

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:19:25', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '36ff991b-31ca-4669-a072-ed1b6eca45a2'	System	16 Sep 2020 23:20:02
User entered 'No (N)'	System	16 Sep 2020 23:20:02

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:19:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '36ff991b-31ca-4669-a072-ed1b6eca45a2'	System	16 Sep 2020 23:20:02
User entered 'None (1)'	System	16 Sep 2020 23:20:02

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:19:59', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '36ff991b-31ca-4669-a072-ed1b6eca45a2'	System	16 Sep 2020 23:20:02
User entered '16 Sep 2020 19:19'	System	16 Sep 2020 23:20:02

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 6'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '544d8bbb-f2ac-479d-877b-3c9615112567'	System	17 Sep 2020 16:55:43
User entered 'None (1)'	System	17 Sep 2020 16:55:43

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:26', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '544d8bbb-f2ac-479d-877b-3c9615112567'	System	17 Sep 2020 16:55:43
User entered 'No (N)'	System	17 Sep 2020 16:55:43

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '544d8bbb-f2ac-479d-877b-3c9615112567'	System	17 Sep 2020 16:55:43
User entered 'No (N)'	System	17 Sep 2020 16:55:43

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:32', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '544d8bbb-f2ac-479d-877b-3c9615112567'	System	17 Sep 2020 16:55:43
User entered 'None (1)'	System	17 Sep 2020 16:55:43

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '544d8bbb-f2ac-479d-877b-3c9615112567'	System	17 Sep 2020 16:55:43
User entered '17 Sep 2020 12:55'	System	17 Sep 2020 16:55:43

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 7'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:00:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '5c59daa1-d0c2-4e8e-8853-346df85abd9e'	System	19 Sep 2020 04:04:14
User entered 'None (1)'	System	19 Sep 2020 04:04:14

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:01:04', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '5c59daa1-d0c2-4e8e-8853-346df85abd9e'	System	19 Sep 2020 04:04:14
User entered 'No (N)'	System	19 Sep 2020 04:04:14

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:01:12', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '5c59daa1-d0c2-4e8e-8853-346df85abd9e'	System	19 Sep 2020 04:04:14
User entered 'No (N)'	System	19 Sep 2020 04:04:14

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:01:21', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '5c59daa1-d0c2-4e8e-8853-346df85abd9e'	System	19 Sep 2020 04:04:14
User entered 'None (1)'	System	19 Sep 2020 04:04:14

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:01:32', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '5c59daa1-d0c2-4e8e-8853-346df85abd9e'	System	19 Sep 2020 04:04:14
User entered '19 Sep 2020 00:01'	System	19 Sep 2020 04:04:14

US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 14:36'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 17:06'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '12 Sep 2020 18:01'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 2'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:45', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:12:48', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:13:01', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:13:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:13:33', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'None (0)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:13:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered 'No (N)'	System	14 Sep 2020 13:13:50

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-14T09:13:47', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '716d51a4-cfd6-43d1-abe3-4878a7b6c5d7'	System	14 Sep 2020 13:13:50
User entered '14 Sep 2020 09:13'	System	14 Sep 2020 13:13:50



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 3'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 4'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:19', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:24', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:28', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:32', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'None (0)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:41:51', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered 'No (N)'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-15T20:42:01', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '1fa14674-f121-419d-a703-9eb1f596428d'	System	16 Sep 2020 00:42:06
User entered '15 Sep 2020 20:42'	System	16 Sep 2020 00:42:06

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 5'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:09', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:16', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:21', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:43', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'None (0)'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:20:49', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered 'No (N)'	System	16 Sep 2020 23:21:26



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-16T19:21:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '165b883d-ad33-4761-9595-36ecd5ed74b7'	System	16 Sep 2020 23:21:26
User entered '16 Sep 2020 19:21'	System	16 Sep 2020 23:21:26

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 6'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:50', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:55:57', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:04', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:15', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:18', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'None (0)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:25', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered 'No (N)'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-17T12:56:37', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'cc14251e-bf8a-4b82-b0a7-c0e4d35eaebe'	System	17 Sep 2020 16:56:40
User entered '17 Sep 2020 12:56'	System	17 Sep 2020 16:56:40

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	12 Sep 2020 18:55:09
User entered 'Day 7'	System	12 Sep 2020 18:55:09

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:02:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:02:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:02:42', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:02:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:03:25', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:03:31', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'None (0)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:03:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered 'No (N)'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b6e332e68d7dd596)', Time: '2020-09-19T00:03:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4e198699-bed3-4a95-9bec-86710465708c'	System	19 Sep 2020 04:05:31
User entered '19 Sep 2020 00:03'	System	19 Sep 2020 04:05:31

US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:55:09



US3222089

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:08:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:55:09

US3222089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:46:55

US3222089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '19 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:46:55

US3222089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:46:55

US3222089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:46:55

US3222089

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:47:11

**US3222089**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	14 Oct 2020 15:47:11

US3222089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:47:27



US3222089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '26 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:47:27

US3222089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:47:27

US3222089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:47:27

US3222089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:47:39

US3222089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	14 Oct 2020 15:47:39

US3222089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:48:38

US3222089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '3 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:48:38

US3222089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:48:38



US3222089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:48:38

US3222089

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:48:50

**US3222089**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	14 Oct 2020 15:48:50

US3222089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:51:33

US3222089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered '13 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:33

US3222089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[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 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered 'Clinic (Clinic)'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:33

**US3222089**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered 'VISIT3'	System	14 Oct 2020 15:51:33

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 15:51:39



US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

**US3222089**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:08:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

**US3222089**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:08:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Oct 2020 15:51:39



US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered empty.	System	14 Oct 2020 15:51:39

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17

US3222089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17



US3222089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:43

US3222089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:53
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:51:43

US3222089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:51:54

US3222089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '13 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:54

US3222089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11:55'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:51:54

US3222089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '13 Oct 2020 11:55'	System	14 Oct 2020 15:51:54

US3222089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	14 Oct 2020 15:51:59

US3222089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:17
User entered '1'	System	14 Oct 2020 15:51:59



US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 64'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 21:17:14

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 71'	System	11 Aug 2020 21:17:14

US3222089

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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**Generated On: 09 Jun 2021 16:08:08**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



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

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

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[Please 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 06:17:18
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**Folder: Safety Follow Up Diary (1)**

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 21:17:14

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 21:17:14



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

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**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 78'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

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**Generated On: 09 Jun 2021 16:08:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please 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 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 21:17:14

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:05:05
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 92'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-12T06:36:56', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'ec062c94-041d-413b-8546-ff74dc0b07a5'	System	12 Nov 2020 11:37:32
User entered 'No (N)'	System	12 Nov 2020 11:37:32

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-12T06:37:11', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'ec062c94-041d-413b-8546-ff74dc0b07a5'	System	12 Nov 2020 11:37:32
User entered 'No (N)'	System	12 Nov 2020 11:37:32

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-12T06:37:27', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'ec062c94-041d-413b-8546-ff74dc0b07a5'	System	12 Nov 2020 11:37:32
User entered '12 Nov 2020 06:37:27'	System	12 Nov 2020 11:37:32



US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered 'Day 99'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-18T16:51:19', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0dd3fc6d-8a40-4d14-8a1f-05a347239e82'	System	18 Nov 2020 21:51:41
User entered 'No (N)'	System	18 Nov 2020 21:51:41

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-18T16:51:26', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0dd3fc6d-8a40-4d14-8a1f-05a347239e82'	System	18 Nov 2020 21:51:41
User entered 'No (N)'	System	18 Nov 2020 21:51:41

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-18T16:51:36', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0dd3fc6d-8a40-4d14-8a1f-05a347239e82'	System	18 Nov 2020 21:51:41
User entered '18 Nov 2020 16:51:36'	System	18 Nov 2020 21:51:41

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 21:17:14

US3222089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:13:20
Data entry locked.	System	11 Aug 2020 21:17:14
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 21:17:14



**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-11-21T15:58:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'be749120-7b9c-406a-a6c7-8454286ecb51'	System	21 Nov 2020 20:59:09
User entered 'No (N)'	System	21 Nov 2020 20:59:09

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-11-21T15:58:53', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'be749120-7b9c-406a-a6c7-8454286ecb51'	System	21 Nov 2020 20:59:09
User entered 'No (N)'	System	21 Nov 2020 20:59:09

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-21T15:59:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'be749120-7b9c-406a-a6c7-8454286ecb51'	System	21 Nov 2020 20:59:09
User entered '21 Nov 2020 15:59:02'	System	21 Nov 2020 20:59:09

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-11-30T16:11:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4ff7ed96-7237-4a0b-aed5-0742c02d9792'	System	30 Nov 2020 21:11:54
User entered 'No (N)'	System	30 Nov 2020 21:11:54



US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-11-30T16:11:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4ff7ed96-7237-4a0b-aed5-0742c02d9792'	System	30 Nov 2020 21:11:54
User entered 'No (N)'	System	30 Nov 2020 21:11:54

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-11-30T16:11:49', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '4ff7ed96-7237-4a0b-aed5-0742c02d9792'	System	30 Nov 2020 21:11:54
User entered '30 Nov 2020 16:11:49'	System	30 Nov 2020 21:11:54

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-12-03T15:15:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '703d11df-d6b6-4414-92c0-7b384ea1106e'	System	03 Dec 2020 20:16:08
User entered 'Yes (Y)'	System	03 Dec 2020 20:16:08

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-12-03T15:15:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '703d11df-d6b6-4414-92c0-7b384ea1106e'	System	03 Dec 2020 20:16:08
User entered 'No (N)'	System	03 Dec 2020 20:16:08

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-03T15:15:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '703d11df-d6b6-4414-92c0-7b384ea1106e'	System	03 Dec 2020 20:16:08
User entered 'No (N)'	System	03 Dec 2020 20:16:08



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-03T15:15:42', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '703d11df-d6b6-4414-92c0-7b384ea1106e'	System	03 Dec 2020 20:16:08
User entered 'No (N)'	System	03 Dec 2020 20:16:08

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

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**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-03T15:16:04', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '703d11df-d6b6-4414-92c0-7b384ea1106e' User entered '03 Dec 2020 15:16:04'	System	03 Dec 2020 20:16:08
	System	03 Dec 2020 20:16:08

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:05:05

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:05:05

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-12-14T14:57:02', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '22f0e9ea-680f-4909-8563-626c2ce8003e'	System	14 Dec 2020 19:57:15
User entered 'No (N)'	System	14 Dec 2020 19:57:15

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-12-14T14:56:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '22f0e9ea-680f-4909-8563-626c2ce8003e'	System	14 Dec 2020 19:57:15
User entered 'No (N)'	System	14 Dec 2020 19:57:15

**US3222089**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-14T14:57:10', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '22f0e9ea-680f-4909-8563-626c2ce8003e'	System	14 Dec 2020 19:57:15
User entered '14 Dec 2020 14:57:10'	System	14 Dec 2020 19:57:15



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-12-17T10:08:18', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '635a2105-97d6-4029-b1d6-f8a1434eb5d2'	System	17 Dec 2020 15:08:38
User entered 'No (N)'	System	17 Dec 2020 15:08:38

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-12-17T10:08:23', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '635a2105-97d6-4029-b1d6-f8a1434eb5d2'	System	17 Dec 2020 15:08:38
User entered 'No (N)'	System	17 Dec 2020 15:08:38

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-17T10:08:30', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '635a2105-97d6-4029-b1d6-f8a1434eb5d2'	System	17 Dec 2020 15:08:38
User entered '17 Dec 2020 10:08:30'	System	17 Dec 2020 15:08:38

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2020-12-26T11:31:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '912a8f97-649e-4ed2-8ec0-317714a3ffa7'	System	26 Dec 2020 16:31:40
User entered 'No (N)'	System	26 Dec 2020 16:31:40

US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2020-12-26T11:31:29', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '912a8f97-649e-4ed2-8ec0-317714a3ffa7'	System	26 Dec 2020 16:31:40
User entered 'No (N)'	System	26 Dec 2020 16:31:40

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2020-12-26T11:31:36', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '912a8f97-649e-4ed2-8ec0-317714a3ffa7'	System	26 Dec 2020 16:31:40
User entered '26 Dec 2020 11:31:36'	System	26 Dec 2020 16:31:40

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-01-03T04:17:03', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd4d3d35e-08ff-48e6-aec1-c6f8d4a4b3a5'	System	03 Jan 2021 09:17:25
User entered 'No (N)'	System	03 Jan 2021 09:17:25



US3222089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-01-03T04:17:14', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd4d3d35e-08ff-48e6-aec1-c6f8d4a4b3a5'	System	03 Jan 2021 09:17:25
User entered 'No (N)'	System	03 Jan 2021 09:17:25

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-03T04:17:22', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'd4d3d35e-08ff-48e6-aec1-c6f8d4a4b3a5'	System	03 Jan 2021 09:17:25
User entered '03 Jan 2021 04:17:22'	System	03 Jan 2021 09:17:25

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-01-08T20:22:32', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'Yes (Y)'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-01-08T20:22:41', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'No (N)'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:22:54', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'Yes (Y)'	System	09 Jan 2021 01:24:55



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '1'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '1'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:07', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '0'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:26', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:23:44', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'Yes (Y)'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:24:24', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-08T20:24:45', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '51039078-f64e-42e3-8b7c-40ed5559cb35'	System	09 Jan 2021 01:24:55
User entered '08 Jan 2021 20:24:45'	System	09 Jan 2021 01:24:55

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-01-21T12:08:51', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0051487b-702d-42a6-b156-ad4dae79612d'	System	21 Jan 2021 17:09:17
User entered 'No (N)'	System	21 Jan 2021 17:09:17

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-01-21T12:09:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0051487b-702d-42a6-b156-ad4dae79612d'	System	21 Jan 2021 17:09:17
User entered 'No (N)'	System	21 Jan 2021 17:09:17

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-21T12:09:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '0051487b-702d-42a6-b156-ad4dae79612d' User entered '21 Jan 2021 12:09:13'	System	21 Jan 2021 17:09:17

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-01-29T20:03:34', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered 'Yes (Y)'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-01-29T20:03:39', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered 'No (N)'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-29T20:03:48', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered 'No (N)'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-29T20:03:56', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered 'Yes (Y)'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-29T20:04:06', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-01-29T20:04:13', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '037488ee-cea0-405a-9770-5a8f1a2c5009'	System	30 Jan 2021 01:04:24
User entered '29 Jan 2021 20:04:13'	System	30 Jan 2021 01:04:24

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-02-08T04:26:46', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'abacecb3-dcbe-406e-b7f8-51461bbf251b'	System	08 Feb 2021 09:27:03
User entered 'No (N)'	System	08 Feb 2021 09:27:03

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-02-08T04:26:52', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'abacecb3-dcbe-406e-b7f8-51461bbf251b'	System	08 Feb 2021 09:27:03
User entered 'No (N)'	System	08 Feb 2021 09:27:03

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-02-08T04:27:01', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: 'abacecb3-dcbe-406e-b7f8-51461bbf251b'	System	08 Feb 2021 09:27:03
User entered '08 Feb 2021 04:27:01'	System	08 Feb 2021 09:27:03

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-02-22T14:53:09', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7210668e-6fc2-4570-aeaa-371609fb8fc4'	System	22 Feb 2021 21:12:20
User entered 'No (N)'	System	22 Feb 2021 21:12:20

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-02-22T14:53:14', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7210668e-6fc2-4570-aeaa-371609fb8fc4'	System	22 Feb 2021 21:12:20
User entered 'No (N)'	System	22 Feb 2021 21:12:20

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-02-22T14:53:20', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '7210668e-6fc2-4570-aeaa-371609fb8fc4'	System	22 Feb 2021 21:12:20
User entered '22 Feb 2021 14:53:20'	System	22 Feb 2021 21:12:20

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-03-12T19:14:31-05:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '817396bd-ddd8-43c2-96f2-9b12dbfa7e75'	System	13 Mar 2021 00:14:52
User entered 'No (N)'	System	13 Mar 2021 00:14:52



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:08

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-03-12T19:14:40-05:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '817396bd-ddd8-43c2-96f2-9b12dbfa7e75'	System	13 Mar 2021 00:14:52
User entered 'No (N)'	System	13 Mar 2021 00:14:52

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-03-12T19:14:49-05:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '817396bd-ddd8-43c2-96f2-9b12dbfa7e75'	System	13 Mar 2021 00:14:52
User entered '12 Mar 2021 19:14:49'	System	13 Mar 2021 00:14:52

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[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 (791b63064df19e3a)', Time: '2021-04-10T06:51:01-04:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '64e44e51-8cc4-4756-8fc3-bb8f0f15178f' User entered 'No (N)'	System	10 Apr 2021 10:51:19

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

Have you been exposed to someone with 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 (791b63064df19e3a)', Time: '2021-04-10T06:51:06-04:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '64e44e51-8cc4-4756-8fc3-bb8f0f15178f' User entered 'No (N)'	System	10 Apr 2021 10:51:19



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-04-10T06:51:16-04:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '64e44e51-8cc4-4756-8fc3-bb8f0f15178f' User entered '10 Apr 2021 06:51:16'	System	10 Apr 2021 10:51:19
	System	10 Apr 2021 10:51:19

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:05:05



**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:05:05

**US3222089**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:08:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:05:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:05:05



US3222089

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:08:08**

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 06:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-03-10T20:59:17-05:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6c15a4ed-abe3-4726-abc2-54a3cb65b9c6'	System	11 Mar 2021 01:59:30
User entered 'No (N)'	System	11 Mar 2021 01:59:30

US3222089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:08:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (791b63064df19e3a)', Time: '2021-03-10T20:59:26-05:00', User OID: 'PatientReportedOutcome (US3222089)', ODM File OID: '6c15a4ed-abe3-4726-abc2-54a3cb65b9c6'	System	11 Mar 2021 01:59:30
User entered '10 Mar 2021 20:59:26'	System	11 Mar 2021 01:59:30

US3222089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Nov 2020 17:13:34

US3222089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '05 Nov 2020'	Jennifer Dittman (b) (4)	09 Nov 2020 17:13:34

US3222089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	09 Nov 2020 17:13:34

US3222089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Jennifer Dittman (b) (4)	09 Nov 2020 17:13:34

US3222089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Nov 2020 17:13:39

US3222089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:47:09
User entered 'I'	System	09 Nov 2020 17:13:39



US3222089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	heather jackson (b) (4)	10 Dec 2020 13:31:03

US3222089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '10 Dec 2020'	heather jackson (b) (4)	10 Dec 2020 13:31:03

US3222089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	10 Dec 2020 13:31:03

US3222089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	heather jackson (b) (4)	10 Dec 2020 13:31:03

US3222089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:40:50

US3222089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User entered 'I'	System	06 Jan 2021 18:40:50

**US3222089**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:43:50

US3222089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
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).	(b) (4)	07 Jan 2021 13:29:59
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	07 Jan 2021 13:29:59
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 13:29:59
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	06 Jan 2021 18:43:50
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 18:43:50



US3222089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:43:50

US3222089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:43:50

US3222089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 13:30:13

US3222089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User entered 'I'	System	07 Jan 2021 13:30:13

**US3222089**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:01

**US3222089**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '06 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:01

US3222089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:01

US3222089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:01



US3222089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:06

US3222089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:32
User entered 'I'	System	03 Mar 2021 11:57:06

**US3222089**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:43

US3222089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:43

US3222089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:43

US3222089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'VISIT4'	System	03 Mar 2021 11:57:43

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50



US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

**US3222089**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:08:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50



US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered empty.	System	31 Mar 2021 12:35:50

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28

US3222089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28

US3222089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:56



US3222089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:57:56

US3222089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:58:36

US3222089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:58:36

US3222089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '15:40'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:58:36

US3222089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered '02 Mar 2021 15:40'	System	03 Mar 2021 11:58:36

US3222089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:58:20

US3222089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:04:28
User entered 'I'	System	03 Mar 2021 11:58:20

US3222089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:07



US3222089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:07

US3222089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:07

US3222089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:07

US3222089

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:15

**US3222089**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 12:49:15

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:15

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:15

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:15



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 21:26:15

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:35:40
User entered '19 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 19:35:40
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

**US3222089**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:08:08**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered '0'	(b) (4) Diana Toney (b) (4)	16 Mar 2021 10:10:56
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:48:57

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Diana Toney (b) (4)	16 Mar 2021 10:10:56
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 03:48:57

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Per CDM: Per IRT, subject was unblinded on 19FEB2021. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:16:46
Query 'Per CDM: Per IRT, subject was unblinded on 19FEB2021. Please review and reconcile.' answered with 'this is the date already entered' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:36:37
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 19:35:40
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	08 Apr 2021 19:35:40
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 15:26:21
Signature has been broken.	Albert Garcia (b) (4) (b) (4)	08 Apr 2021 15:26:21
User entered '19 Feb 2021' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Apr 2021 15:26:21
User opened query 'Per CDM: Per IRT, subject was unblinded on 19FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:51:57
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	02 Mar 2021 21:30:33
User entered '02 Mar 2021'	Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:30:33
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '1'	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'I'	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered empty.	System	02 Mar 2021 21:28:45
DataPoint set to visible.	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered empty.	System	02 Mar 2021 21:28:45
DataPoint set to visible.	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered '15:40' reason for change: Data Entry Error	Diana Toney (b) (4)	16 Mar 2021 10:18:56
User entered '15:35' reason for change: Data Entry Error	Diana Toney (b) (4)	16 Mar 2021 10:17:57
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	15 Mar 2021 12:58:09
Signature has been broken.	(b) (4), (b) (6)	15 Mar 2021 12:58:09
User entered '15:45' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 12:58:09
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	03 Mar 2021 11:53:44
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '15:55'	Diana Toney (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '02 Mar 2021 15:40'	System	16 Mar 2021 10:18:56
User entered '02 Mar 2021 15:35'	System	16 Mar 2021 10:17:57
User entered '02 Mar 2021 15:45'	System	15 Mar 2021 12:58:09
User entered '02 Mar 2021 15:55'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '36.7' C	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '64'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'bpm'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '18'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'breaths/min'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '107'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'mmHg'	System	02 Mar 2021 21:28:45



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '69'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'mmHg'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered empty.	System	02 Mar 2021 21:28:45
DataPoint set to visible.	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '16:20'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '02 Mar 2021 16:20'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '36.7' C	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '62'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'bpm'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '18'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'breaths/min'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '124'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'mmHg'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '77'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'mmHg'	System	02 Mar 2021 21:28:45

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:56

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:32:06
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 21:28:56

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44

US3222089

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:08:08**

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)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'mRNA-1273'	System	03 Mar 2021 11:53:44
DataPoint set to visible.	System	02 Mar 2021 21:26:50

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '15:49'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '02 Mar 2021 15:49'	System	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'ONCE'	System	03 Mar 2021 11:53:44



US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 11:53:44

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:13

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:13

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '15:35'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:13

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '02 Mar 2021 15:35'	System	03 Mar 2021 11:54:13

**US3222089**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:08:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:36

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 12:03:05
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'Subject ID: US3222089 Accession Number: 1F66073 Gender: Female YOB: 1947 Visit: OL-1 Drawdate: 02-Mar-2021 ' (Site from DM).	Jennifer Dittman (b) (4) (b) (4)	24 Mar 2021 20:14:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:00:39
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:07:35
User entered '02 Mar 2021'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:36

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '15:37'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:36



**US3222089**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:08:08**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered '02 Mar 2021 15:37'	System	03 Mar 2021 11:54:36

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 11:54:40

US3222089

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:01:27
User entered 'I'	System	03 Mar 2021 11:54:40

**US3222089**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:16

**US3222089**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:16

US3222089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:16

US3222089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:16

US3222089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:14:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:22



US3222089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User entered 'I'	System	09 Mar 2021 19:50:22

US3222089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:36
User entered '1'	System	09 Mar 2021 19:50:22
DataPoint set to visible.	System	09 Mar 2021 19:50:22

US3222089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	09 Apr 2021 20:16:10
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '09 Apr 2021'	Diana Toney (b) (4)	09 Apr 2021 20:16:10
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	09 Apr 2021 20:16:10
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:08:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 20:16:10

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	



US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '09 Apr 2021'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '14:10'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 14:10'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '36.4' C	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Oral (Oral)'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '65'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 20:17:50



US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '18'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '116'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '80'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	



US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '09 Apr 2021'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '15:00'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 15:00'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '37.1' C	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Oral (Oral)'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '64'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 20:17:50



US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	09 Apr 2021 20:18:06
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	09 Apr 2021 20:18:06
User entered '18' reason for change: Data Entry Error	Diana Toney (b) (4)	09 Apr 2021 20:18:06
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	09 Apr 2021 20:17:50
User entered '1'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '111'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '76'	Diana Toney (b) (4)	09 Apr 2021 20:17:50
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 20:17:50

US3222089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	09 Apr 2021 20:18:20
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '09 Apr 2021'	Diana Toney (b) (4)	09 Apr 2021 20:18:20
	(b) (4)	



US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 20:18:40
DataPoint set to visible.	System	09 Mar 2021 19:50:22

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '09 Apr 2021'	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '14:29'	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	

**US3222089**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:08:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 14:29'	System	09 Apr 2021 20:18:40

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Diana Toney (b) (4)	09 Apr 2021 20:18:40
	(b) (4)	



US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 20:18:40

US3222089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 20:18:40

US3222089

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:34:43

**US3222089**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 13:34:43

**US3222089**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:35:06

US3222089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 12:29:54
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD ENTERED ON LOG OOW' (Site from System).	douglas winter (b) (4) (b) (4)	21 Apr 2021 15:01:20
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Apr 2021 20:18:40
User entered '06 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 13:35:06

**US3222089**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:35:06

**US3222089**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:08:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:35:06



US3222089

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:35:13

**US3222089**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:08:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 13:35:13

US3222089

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:08:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:53
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'SHE SAW HER PCP' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:35:23
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:59:19
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 17:41:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:38:23
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:52:30
	Crystal Paccione (b) (4) (b) (4)	11 Aug 2020 21:47:27

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:10:55
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'SUBJECT WAS NOT ASSESSED FOR COVID-19' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:51:26
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:52:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:41:34
Data point term sent to Coder	System	09 Nov 2020 18:40:28
User entered 'SORE THROAT'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29



**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '31 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User entered empty.	System	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '04 Nov 2020'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User entered empty.	System	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29



US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29



US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

US3222089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Not Related (NOT RELATED)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Not Related (NOT RELATED)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'None (NONE)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'I'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29



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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:39:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User entered '0'	System	09 Nov 2020 18:39:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10
User entered 'I'	System	09 Nov 2020 18:39:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:10

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Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:03
User entered	System	26 Jan 2021 17:34:58
'USA-US104-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	26 Jan 2021 17:34:58



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:08:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'PV Query: Please confirm if COPD exacerbation/pneumonia should be listed as 2 separate SAEs.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:56:01
Query 'PV Query: Please confirm if COPD exacerbation/pneumonia should be listed as 2 separate SAEs.' answered with 'DISCHARGE SUMMARY DOES NOT INDICATE PNEUMONIA AS A DIAGNOSIS BUT IT DOES SAY SHE WAS IN ACUTE DIASTOLIC HEART FAILURE AS A PRIMARY AND COPD EXACERBATION AS A SECONDARY.' (Site from Safety).	douglas winter (b) (4) (b) (4)	20 Apr 2021 20:10:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:40:47
Data point term sent to Coder	System	09 Apr 2021 19:39:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:39:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:39:45
Query 'For coding purposes, please split COPD EXACERBATION/PNEUMONIA into separate entries.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:39:40
Data point term sent to Coder	System	09 Apr 2021 19:38:48
DataPoint Un-verified.	Jennifer Dittman (b) (4) (b) (4)	09 Apr 2021 19:38:18
User entered 'COPD EXACERBATION' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	09 Apr 2021 19:38:18
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if COPD exacerbation/pneumonia should be listed as 2 separate SAEs.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 13:42:51
User opened query 'For coding purposes, please split COPD EXACERBATION/PNEUMONIA into separate entries.' (Site from System).	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:14:51
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:44:33
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'UPDATED CAUSE' (Site from Safety).	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:33:24
Data point term sent to Coder	System	03 Mar 2021 13:33:16
Coding entries removed.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:32:28
User entered 'COPD EXACERBATION/PNEUMONIA' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:32:28
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:38:06
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:40:58
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'confirmed negative for covid-19' (Site from DM).	Diana Toney (b) (4) (b) (4)	20 Feb 2021 16:27:40
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 18:29:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:53:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:53:55
Data point term sent to Coder	System	25 Jan 2021 21:53:22
User entered 'SHORTNESS OF BREATH'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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EAB) (1725)

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Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '23 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	20 Feb 2021 16:32:56
User entered '24 Jan 2021'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:08:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Jan 2021 21:53:03
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:53:03
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Jan 2021 21:52:39
User entered '11:30'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:08:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 21:53:03
User entered '24 Jan 2021 11:30'	System	25 Jan 2021 21:52:39



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 13:32:47
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:32:47
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 13:32:28
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:44:47
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED TO NO' (Site from Safety).	Diana Toney (b) (4)	03 Mar 2021 13:33:40
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	03 Mar 2021 13:32:28
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:36:54
User entered empty.	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:54:49
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 'end date added' (Site from Safety).	Diana Toney (b) (4)	20 Feb 2021 17:07:17
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:30:06
User entered empty.	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 21:52:39

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:01:05
User closed query 'Source indicates this was grade 4. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:01:03
Query 'Source indicates this was grade 4. Please confirm and revise if necessary.' answered with 'CORRECTED' (Site from CRA).	douglas winter (b) (4)	12 Apr 2021 11:46:28
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:42:03
	(b) (4)	
User opened query 'Source indicates this was grade 4. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:34:19
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:58
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 21:53:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 21:52:39
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39



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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 02:32:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4)	25 Jan 2021 21:53:11
	(b) (4)	
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		25 Jan 2021 21:53:03
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		25 Jan 2021 21:53:03
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	25 Jan 2021 21:53:03
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	25 Jan 2021 21:53:03
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	25 Jan 2021 21:52:39
User entered '0'	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:01:28
User closed query 'Medical records indicate subject was admitted on 24Jan2021 at 0050. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:01:26
User entered '24 Jan 2021' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:47:03
	(b) (4)	
Query 'Medical records indicate subject was admitted on 24Jan2021 at 0050. Please confirm and revise if necessary.' answered with 'CORRECTED DATE' (Site from CRA).	douglas winter (b) (4)	12 Apr 2021 11:46:48
	(b) (4)	
User opened query 'Medical records indicate subject was admitted on 24Jan2021 at 0050. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:39:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 17:38:58
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '23 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	20 Feb 2021 16:32:33
	(b) (4)	
User entered '24 Jan 2021'	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Hospital admission and discharge dates for COPD exacerbation is reported as 24 Jan 2021 - 27 Jan 2021. Hospital dates for acute diastolic heart failure was reported as 23 Jan 2021. Please confirm hospital admission and discharge dates and update as necessary.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:31:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:54:57
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	Diana Toney (b) (4)	20 Feb 2021 16:34:52
User entered '27 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	20 Feb 2021 16:32:33
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:29:47
User entered empty.	douglas winter (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:08:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	20 Feb 2021 16:32:33
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		20 Feb 2021 16:32:33
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	20 Feb 2021 16:32:33
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	25 Jan 2021 21:52:39
User entered 'Unknown (UNK)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39



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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 08:44:36
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'THERE IS NOW. LOL' (Site from DM).	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:55:13
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:03:40
User entered 'I'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered '0'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:45:11
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'RECOVERED AND RESOLVED' (Site from Safety).	Diana Toney (b) (4)	03 Mar 2021 13:34:08
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Diana Toney (b) (4)	03 Mar 2021 13:32:28
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:30:36
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4)	25 Jan 2021 21:52:39
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:33:46
User entered empty.	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39



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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Hospital admission and discharge dates for COPD exacerbation is reported as 24 Jan 2021 - 27 Jan 2021. Hospital dates for acute diastolic heart failure was reported as 23 Jan 2021. Please confirm hospital admission and discharge dates and update as necessary.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:31:06
User opened query 'PV Query: Hospital admission and discharge dates for COPD exacerbation is reported as 24 Jan 2021 - 27 Jan 2021. Hospital dates for acute diastolic heart failure was reported as 23 Jan 2021. Please confirm hospital admission and discharge dates and update as necessary.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:02:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'REDACTED RECORDS WERE SENT ON 21/FEB/2021 TO SAFETY.' (Site from Safety).	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:58:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:46
User closed query 'PV Query: Please confirm if a pulmonary function test was performed. If so, please provide the results when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:45:34
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:45:24

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if a pulmonary function test was performed. If so, please provide the results when available.' answered with 'PFT RECOMMENDED FROM HOSP RECORDS TO BE OUTPATIENT EXAM' (Site from Safety).	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:36:51
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'IT WAS UPDATED' (Site from Safety).	Diana Toney (b) (4) (b) (4)	03 Mar 2021 13:34:40
User opened query 'PV Query: Please confirm if a pulmonary function test was performed. If so, please provide the results when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:38:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:55:17
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)	22 Feb 2021 18:55:10
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 con med sheet and crf' (Site from Safety).	Diana Toney (b) (4) (b) (4)	20 Feb 2021 17:13:20
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 'sars cov2 pcr negative on 01/23/2021' (Site from Safety).	Diana Toney (b) (4) (b) (4)	20 Feb 2021 17:08:45

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:31:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:31:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:30:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:29:29
User entered 'I WAS INFORMED BY OUR CALL CENTER THAT THE PATIENT IS IN THE HOSPITAL. I've CALLED AND LEFT MESSAGES AND STILL HAVENT RECEIVED A RETURN CALL.'	douglas winter (b) (4) (b) (4)	25 Jan 2021 21:52:39

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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:52:39

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 21:52:39

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 21:52:39

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:46:59
User entered 'USA-US104-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	21 Apr 2021 17:46:51

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider removing "sae" from event term, primary saeacute diastolic heart failure.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:30:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute diastolic heart failure - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 12:21:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 12:21:10
Data point term sent to Coder	System	20 Apr 2021 20:15:08
User entered 'PRIMARY SAE ACUTE DIASTOLIC HEART FAILURE'	douglas winter (b) (4)	20 Apr 2021 20:14:21



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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '23 Jan 2021'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:14:21

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '27 Jan 2021'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	



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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:14:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	20 Apr 2021 20:14:50
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Apr 2021 20:14:21
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

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Folder: Adverse Events

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Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 20:14:50
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	20 Apr 2021 20:14:50
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	20 Apr 2021 20:14:50
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 20:14:21
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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Generated On: 09 Jun 2021 16:08:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '23 Jan 2021'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	



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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '23 Jan 2021'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered empty.	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 13:40:57
User entered '0'	douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21



US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered '0'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 13:40:57
User entered 'I'	douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
User entered 'I'	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

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 13:40:57
	(b) (4)	
User entered empty.	douglas winter (b) (4)	20 Apr 2021 20:14:21
	(b) (4)	

US3222089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ADDING ACUTE DIASTOLIC HEART FAILURE AS A SECONDARY AE'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:14:21

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 20:14:21



**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 20:14:21

**US3222089**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 20:14:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:08:08

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:57:38
User closed query 'Please physically enter conmeds on "prior/concomitant medication and vaccination" eCRF and not within the query response. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:57:37
Query 'Please physically enter conmeds on "prior/concomitant medication and vaccination" eCRF and not within the query response. ' answered with 'CONMEDS ENTERED' (Site from CRA).	douglas winter (b) (4) (b) (4)	21 Apr 2021 15:00:42
User opened query 'Please physically enter conmeds on "prior/concomitant medication and vaccination" eCRF and not within the query response. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:38:06
User closed query 'Subject has many con-meds while in hospital, starting on page 16 of discharge summary. Please enter those here.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:38:06
Query 'Subject has many con-meds while in hospital, starting on page 16 of discharge summary. Please enter those here.' answered with 'acetaminophen, aripiprazole, azithromycin, benzonatate, budesonide, ceftriaxone, codeine-guaifenesin, Colace, centrum, diphenhydramine, doxepin, famotidine, formoterol, furosemide, ipratropium, methiprednisolone, metoprolol tartrate, miralax, mucinex, multiple vitamins with iron oral tablet, nicotine transdermal film, ondansetron, spironolactone, valsartan , venlafaxine , vitamin c, Xanax, lexapro, ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 17:22:55
User opened query 'Subject has many con-meds while in hospital, starting on page 16 of discharge summary. Please enter those here.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:42:23
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:25:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Sep 2020 13:27:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:27:47
Data point term sent to Coder	System	14 Sep 2020 13:27:02
User entered 'METOPROLOL'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:26:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#2) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:37:48
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#2) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:08:36
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:08:26
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#2) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:57:26
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:26:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	20 Apr 2021 20:39:26
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '25'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'I'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	14 Sep 2020 13:26:51
	(b) (4)	

**US3222089**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:26:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:26:51

**US3222089**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 13:26:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 00:14:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:14:25
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:59 12 Oct 2020 17:09:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
Data point term sent to Coder User entered 'SPRIONOLACTONE'	System Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:29:04 14 Sep 2020 13:28:33

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:37:55
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:19
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:08:50
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:56:54
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:28:33

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'COPD'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '25'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:38:16
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:24
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:19
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:57:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:28:33

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'I'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	14 Sep 2020 13:28:33
	(b) (4)	

**US3222089**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:28:33

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:28:33

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 13:28:33

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: FUROSIMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 17:10:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:10:30
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:58 12 Oct 2020 17:09:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: FUROSIMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:30:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:30:53
Data point term sent to Coder User entered 'FUROSIMIDE'	System Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:30:05 14 Sep 2020 13:29:16



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:38:23
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:49
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:44
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:57:47
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:29:16

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'COPD'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '40'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:38:36
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:55
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 17:09:44
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:58:01
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 13:29:16



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'I'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	14 Sep 2020 13:29:16
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:29:16

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:29:16



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 13:29:16

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: SUBSTITUTED ALKYLAMINES, PRODUCT: CHLORPHENAMINE MALEATE, PRODUCTSYNONYM: EQUATE CHLORTABS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:30:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:30:38
Data point term sent to Coder	System	09 Nov 2020 18:51:39
User entered 'CHLORTABS'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 09:31:15
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	22 Dec 2020 18:52:43
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	22 Dec 2020 18:52:28
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:48:55
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:51:37

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'SEASONAL ALLERGIES'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:51:37

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '4'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'mg (mg)'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'as needed (PRN)'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'UN UNK 2001'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:51:37

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:51:37
	(b) (4)	

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	09 Nov 2020 18:51:37



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:51:37

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:51:37

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:51:37

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, PRODUCT: PENICILLIN NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:30:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:30:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, PRODUCT: PENICILLIN NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 06:05:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 06:05:26
Data point term sent to Coder	System	09 Nov 2020 18:53:40
User entered 'PENICILLIN'	Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'SORE THROAT'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '500'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'mg (mg)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'four times daily (QID)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '31 Oct 2020'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '04 Nov 2020'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	Alicia Cevera (b) (4)	09 Nov 2020 18:53:09

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User entered '4'	System	09 Nov 2020 18:53:09

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User entered '1'	System	09 Nov 2020 18:53:09

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:39
User entered '804 (804)'	System	09 Nov 2020 18:53:09

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 18:00:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 18:00:48
Data point term sent to Coder	System	10 Dec 2020 13:37:56
User entered 'Influenca'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Yes (Y)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Vaccine'	heather jackson (b) (4)	10 Dec 2020 13:37:22



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '.05'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'mL (mL)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'once (ONCE)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:08:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'Intramuscular (INTRAMUSCULAR)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered empty.	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Nov 2020'	heather jackson (b) (4)	10 Dec 2020 13:37:22



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '0'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '11 Nov 2020'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'No (N)'	heather jackson (b) (4)	10 Dec 2020 13:37:22

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User entered empty.	System	10 Dec 2020 13:37:22

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User entered empty.	System	10 Dec 2020 13:37:22

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:28:59
User entered empty.	System	10 Dec 2020 13:37:22

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 20:39:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 20:39:31
Data point term sent to Coder	System	20 Apr 2021 20:38:52
User entered 'ACETAMINOPHEN'	douglas winter (b) (4)	20 Apr 2021 20:38:51



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'FEVER OR PAIN'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '650'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q4HS/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:38:51



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:38:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User entered empty.	System	20 Apr 2021 20:38:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User entered empty.	System	20 Apr 2021 20:38:51



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:55
User entered empty.	System	20 Apr 2021 20:38:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:08:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:08:59
Data point term sent to Coder	System	20 Apr 2021 20:50:11
User entered 'ARIPIPRAZOLE'	douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'MAJOR DEPRESSION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '5'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:49:39



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '23 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 20:49:39



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User entered '1'	System	20 Apr 2021 20:49:39

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User entered '1'	System	20 Apr 2021 20:49:39

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:16
User entered '804 (804)'	System	20 Apr 2021 20:49:39

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:22:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:22:47
Data point term sent to Coder	System	21 Apr 2021 14:18:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:18:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:18:09
Query 'DM-Coding: Please split and report each medication separately on a separate line to capture coding for all reported medications. Example: 1) AZITHROMYCIN 2) BENZONATATE ' canceled (Site from System).	Coder Import (b) (4)	21 Apr 2021 14:17:58
Data point term sent to Coder	System	21 Apr 2021 14:17:08
User entered 'AZITHROMYCIN' reason for change:	douglas winter (b) (4)	21 Apr 2021 14:17:00
Data Entry Error	(b) (4)	
User opened query 'DM-Coding: Please split and report each medication separately on a separate line to capture coding for all reported medications. Example: 1) AZITHROMYCIN 2) BENZONATATE ' (Site from System).	Coder Import (b) (4)	21 Apr 2021 08:17:51
Data point term sent to Coder	System	20 Apr 2021 21:06:46
User entered 'AZITHROMYCIN BENZONATATE'	douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '100'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q8HS'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:06:28

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User entered empty.	System	20 Apr 2021 21:06:28

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User entered empty.	System	20 Apr 2021 21:06:28

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:48
User entered empty.	System	20 Apr 2021 21:06:28

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:15:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:15:02
Data point term sent to Coder	System	20 Apr 2021 21:12:57
User entered 'BUDESONIDE'	douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0.5'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q12HS'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:11:58

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User entered empty.	System	20 Apr 2021 21:11:58

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User entered empty.	System	20 Apr 2021 21:11:58

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:37
User entered empty.	System	20 Apr 2021 21:11:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: CODEINE;GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:46:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:46:07
Data point term sent to Coder	System	20 Apr 2021 21:17:07
User entered 'CEFTRIAZONE (CODEINE-GUAIFENESIN)'	douglas winter (b) (4)	20 Apr 2021 21:16:29



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '10/100/5'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Other (OTHER)'	douglas winter (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'MG/MG/ML'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q4HS'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	douglas winter (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:16:29

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User entered empty.	System	20 Apr 2021 21:16:29

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User entered empty.	System	20 Apr 2021 21:16:29



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:00
User entered empty.	System	20 Apr 2021 21:16:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:23:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:23:58
Data point term sent to Coder	System	20 Apr 2021 21:18:08
User entered 'COLACE'	douglas winter (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE (CONSTIPATION)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '100'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:17:57



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:17:57



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User entered '2'	System	20 Apr 2021 21:17:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User entered '1'	System	20 Apr 2021 21:17:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:33:28
User entered '804 (804)'	System	20 Apr 2021 21:17:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:29:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:29:02
Data point term sent to Coder	System	20 Apr 2021 21:20:10
User entered 'DIPHENHYDRAMINE'	douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '25'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q6HS/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:19:55

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User entered empty.	System	20 Apr 2021 21:19:55

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User entered empty.	System	20 Apr 2021 21:19:55

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:29:24
User entered empty.	System	20 Apr 2021 21:19:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: DOXEPIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 21:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:24:43
Data point term sent to Coder	System	20 Apr 2021 21:23:13
User entered 'DOXEPIN'	douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'DEPRESSION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '100'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:22:14

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User entered '2'	System	20 Apr 2021 21:22:14

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User entered '1'	System	20 Apr 2021 21:22:14

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:30:34
User entered '804 (804)'	System	20 Apr 2021 21:22:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:36:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:36:58
Data point term sent to Coder	System	20 Apr 2021 21:33:28
User entered 'FAMOTIDINE'	douglas winter (b) (4)	20 Apr 2021 21:32:29



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q12HS'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:32:29

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User entered empty.	System	20 Apr 2021 21:32:29

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User entered empty.	System	20 Apr 2021 21:32:29



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:08:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:03
User entered empty.	System	20 Apr 2021 21:32:29

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: FORMOTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:38:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:38:50
Data point term sent to Coder	System	20 Apr 2021 21:34:29
User entered 'FORMOTEROL'	douglas winter (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ug (ug)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:33:51



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User entered '2'	System	20 Apr 2021 21:33:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User entered '1'	System	20 Apr 2021 21:33:51

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:31:40
User entered '804 (804)'	System	20 Apr 2021 21:33:51

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:39:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:39:55
Data point term sent to Coder	System	20 Apr 2021 21:35:30
User entered 'FUROSEMIDE'	douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ACUTE DIASTOLIC HEART FAILURE'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '40'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	20 Apr 2021 21:34:58



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	20 Apr 2021 21:34:58

**US3222089**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User entered '2'	System	20 Apr 2021 21:34:58

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User entered '1'	System	20 Apr 2021 21:34:58

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:32:08
User entered '804 (804)'	System	20 Apr 2021 21:34:58

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:26:42
Data point term sent to Coder	System	21 Apr 2021 14:19:10
User entered 'BENZONATATE'	douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '100'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:18:12

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User entered '3'	System	21 Apr 2021 14:18:12

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User entered '1'	System	21 Apr 2021 14:18:12

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:50
User entered '804 (804)'	System	21 Apr 2021 14:18:12

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:46
Data point term sent to Coder	System	21 Apr 2021 14:21:12
User entered 'IPRATROPIUM'	douglas winter (b) (4)	21 Apr 2021 14:20:57



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0.5'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:20:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User entered '3'	System	21 Apr 2021 14:20:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User entered '1'	System	21 Apr 2021 14:20:57



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:41
User entered '804 (804)'	System	21 Apr 2021 14:20:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:29:59
Data point term sent to Coder	System	21 Apr 2021 14:22:13
User entered 'METHYLPREDNISOLONE'	douglas winter (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '40'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	21 Apr 2021 14:22:27
User entered 'other (OTHER)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:27
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	21 Apr 2021 14:22:11
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q12HS'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:22:11



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User entered empty.	System	21 Apr 2021 14:22:27
User entered '1'	System	21 Apr 2021 14:22:11

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User entered empty.	System	21 Apr 2021 14:22:27
User entered '1'	System	21 Apr 2021 14:22:11

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:45:15
User entered empty.	System	21 Apr 2021 14:22:27
User entered '804 (804)'	System	21 Apr 2021 14:22:11

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 14:34:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 14:34:20
Data point term sent to Coder	System	21 Apr 2021 14:24:14
User entered 'METOPROLOL TARTRATE'	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ACUTE DIASTOLIC HEART FAILURE'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '25'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:23:46

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User entered '2'	System	21 Apr 2021 14:23:46

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User entered '1'	System	21 Apr 2021 14:23:46

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:05
User entered '804 (804)'	System	21 Apr 2021 14:23:46

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:31:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:31:23
Data point term sent to Coder	System	21 Apr 2021 14:25:15
User entered 'MIRALAX'	douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '17'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'g (g)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:08:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User entered '1'	System	21 Apr 2021 14:24:54

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User entered '1'	System	21 Apr 2021 14:24:54

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:29
User entered '804 (804)'	System	21 Apr 2021 14:24:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:31:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:31:40
Data point term sent to Coder	System	21 Apr 2021 14:26:16
User entered 'MUCINEX'	douglas winter (b) (4)	21 Apr 2021 14:25:55



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '600'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:25:55



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:25:55

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User entered '2'	System	21 Apr 2021 14:25:55

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User entered '1'	System	21 Apr 2021 14:25:55



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:53
User entered '804 (804)'	System	21 Apr 2021 14:25:55

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS WITH MINERALS, PRODUCT: IRON;VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:35:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:35:27
Data point term sent to Coder	System	21 Apr 2021 14:28:18
User entered 'MULTIPLE VITAMIN WITH IRON'	douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'COPD EXACERBATION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'tablet (TABLET)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:27:19



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User entered '1'	System	21 Apr 2021 14:27:19

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User entered '1'	System	21 Apr 2021 14:27:19

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:46:40
User entered '804 (804)'	System	21 Apr 2021 14:27:19

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:35:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:35:05
Data point term sent to Coder	System	21 Apr 2021 14:30:19
User entered 'NICOTINE TRANSDERMAL FILM'	douglas winter (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '14'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	douglas winter (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:29:21



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:29:21

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User entered '1'	System	21 Apr 2021 14:29:21

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User entered '1'	System	21 Apr 2021 14:29:21

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:33
User entered '804 (804)'	System	21 Apr 2021 14:29:21

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:02:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:02:10
Data point term sent to Coder	System	21 Apr 2021 14:33:24
User entered 'ONDANSETRON'	douglas winter (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '4'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q4HS/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:32:34

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User entered empty.	System	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:08:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User entered empty.	System	21 Apr 2021 14:32:34

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:58
User entered empty.	System	21 Apr 2021 14:32:34

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:21:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	22 Apr 2021 07:21:51
Data point term sent to Coder	System	21 Apr 2021 14:34:27
User entered 'SALINE FLUSH'	douglas winter (b) (4)	21 Apr 2021 14:34:03
	(b) (4)	



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'KEEP VAIN OPEN'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:34:03



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:34:03

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User entered empty.	System	21 Apr 2021 14:34:03

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User entered empty.	System	21 Apr 2021 14:34:03



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:54
User entered empty.	System	21 Apr 2021 14:34:03

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:56:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 14:56:36
Data point term sent to Coder	System	21 Apr 2021 14:35:28
User entered 'SALINE FLUSH'	douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'KEEP VEIN OPEN'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Q12HS'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:35:14



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User entered empty.	System	21 Apr 2021 14:35:14

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User entered empty.	System	21 Apr 2021 14:35:14

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:20
User entered empty.	System	21 Apr 2021 14:35:14

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:08:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:08:12
Data point term sent to Coder	System	21 Apr 2021 14:38:32
User entered 'SODIUM CHLORIDE 0.9%'	douglas winter (b) (4)	21 Apr 2021 14:37:53
	(b) (4)	

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'PREVENTATIVE'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '250'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once (ONCE)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:37:53

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User entered empty.	System	21 Apr 2021 14:37:53

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User entered empty.	System	21 Apr 2021 14:37:53

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:42:02
User entered empty.	System	21 Apr 2021 14:37:53

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 15:08:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 15:08:11
Data point term sent to Coder	System	21 Apr 2021 14:39:33
User entered 'SPIRONOLACTONE'	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ACUTE DIASTOLIC HEART FAILURE'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:39:31



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '25'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:39:31

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User entered '1'	System	21 Apr 2021 14:39:31

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User entered '1'	System	21 Apr 2021 14:39:31

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:37:26
User entered '804 (804)'	System	21 Apr 2021 14:39:31

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:08:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:08:56
Data point term sent to Coder	System	21 Apr 2021 14:41:34
User entered 'VALSARTAN'	douglas winter (b) (4)	21 Apr 2021 14:41:01



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ACUTE DIASTOLIC HEART FAILURE'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '320'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:41:01

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User entered '1'	System	21 Apr 2021 14:41:01

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User entered '1'	System	21 Apr 2021 14:41:01



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:36:19
User entered '804 (804)'	System	21 Apr 2021 14:41:01

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 16:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:09:41
Data point term sent to Coder	System	21 Apr 2021 14:47:40
User entered 'VENLAFAXINE'	douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'MAJOR DEPRESSION'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '100'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:05



US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User entered '2'	System	21 Apr 2021 14:47:05

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User entered '1'	System	21 Apr 2021 14:47:05

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:52
User entered '804 (804)'	System	21 Apr 2021 14:47:05

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:13:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:13:09
Data point term sent to Coder	System	21 Apr 2021 14:48:41
User entered 'VITAMIN C'	douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '500'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:47:54

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User entered '1'	System	21 Apr 2021 14:47:54

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User entered '1'	System	21 Apr 2021 14:47:54

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:34:54
User entered '804 (804)'	System	21 Apr 2021 14:47:54

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:15:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 15:15:23
Data point term sent to Coder	System	21 Apr 2021 14:51:47
User entered 'XANAX'	douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'ANXIETY'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0.25'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '24 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57



US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '27 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	21 Apr 2021 14:50:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 16:08:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User entered '3'	System	21 Apr 2021 14:50:57

US3222089

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 16:08:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User entered '1'	System	21 Apr 2021 14:50:57

US3222089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:08:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:26
User entered '804 (804)'	System	21 Apr 2021 14:50:57

US3222089

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:08:08**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 16:05:22
	(b) (4)	



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:08:08**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18



**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:08:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered '26/Jan/2021 12:35'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:08:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58

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Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:08:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
User entered '22/Feb/2021 13:57'	(b) (4) System	22 Feb 2021 18:57:28

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:08:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:57:28

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:08:08**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:08:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered '04/Mar/2021 09:46'	(b) (4) System	04 Mar 2021 15:46:14

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:08:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:46:14

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

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[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:08:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '12/Apr/2021 12:37'	(b) (4) System	12 Apr 2021 16:37:25

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:08:08

**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 13:40:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 16:37:25



US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:10
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:36:53
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'USA-US104-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:08:08**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Yes (Y)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58

US3222089

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'No (N)'	System	26 Jan 2021 17:34:58



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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Teresa'	System	26 Jan 2021 17:34:58

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Becker'	System	26 Jan 2021 17:34:58

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
Un-reviewed for Safety.	System	12 Apr 2021 16:37:25
User entered '860 Peachwood Ave'	System	12 Apr 2021 16:37:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '860 PEACHWOOD DR' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '6550 Mapleridge Street'	System	26 Jan 2021 17:34:58

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Folder: SAE USA-US104-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered 'DELAND' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered 'Houston'	System	26 Jan 2021 17:34:58

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Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:47:19
User entered empty.	System	21 Apr 2021 17:46:51
Un-reviewed for Safety.	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
User entered 'FL' reason for change: Data Entry Error	douglas winter (b) (4)	21 Apr 2021 14:59:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
User entered empty.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	

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Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:01
Un-reviewed for Safety.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 11:41:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:35:11
User entered '77081'	System	26 Jan 2021 17:34:58

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:13
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:37:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:57:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:56:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
User entered 'US'	(b) (4) System	26 Jan 2021 17:35:18

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Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 17:47:34
User entered '4'	System	12 Apr 2021 16:37:25
User entered '3'	System	04 Mar 2021 15:46:14
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:10:12
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:57:28
User entered '2'	System	22 Feb 2021 18:57:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:46:47
	(b) (4)	
User entered '1'	System	26 Jan 2021 17:35:18



**US3222089**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:08:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:40:57
User entered '21/Apr/2021 13:47'	(b) (4) System	21 Apr 2021 17:47:34

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Form: Safety Report Form (5)

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**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 13:40:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:47:34