

US3222068 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:47

All time stamps listed in this document are displayed in GMT

US3222068

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

[Participant ID](#)

US3222068

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

US3222068

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3222068

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3222068

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3222068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3222068

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Were any significant conditions reported?

Yes ☒

No ☐

US3222068

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	01 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	01 JAN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	BACK SURGERY
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3222068

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	01 JAN 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	01 JAN 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	HERNIA SURGERY, UMBILICAL
Start date (dd MMM yyyy)	01 JAN 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3222068

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	01 JAN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	KNEE REPLACEMENT - BILAT
Start date (dd MMM yyyy)	01 JAN 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3222068

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3222068

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	PLUMONARY FIBROSIS
Start date (dd MMM yyyy)	01 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	EDEMA - BILAT PEDAL EDEMA
Start date (dd MMM yyyy)	01 JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	CODEINE ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3222068

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	GEMFIBROZIL ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3222068

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	CAT DANDERE ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3222068

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	GRASS ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3222068

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	POLLEN ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3222068

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Condition	ANXIETY
Start date (dd MMM yyyy)	01 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222068

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:50
Height (<i>xxx.x</i>)	167.6 cm
Weight (<i>xxx.x</i>)	97.1 kg
BMI (<i>xxx.x</i>)	34.56776 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222068

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3222068

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3222068

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185407

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 ☒

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Height	ND - Not Done
Weight	ND - Not Done

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:04
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 14:33 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 14:33

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

US3222068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

14:12 (24 HR)

Collection date and time (derived)

10 AUG 2020 14:12

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	10 AUG 2020 14:15
Nasopharyngeal Swab 2	No		

US3222068

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

10 AUG 2020 15:05

PC Open Date & Time

10 AUG 2020 14:53

PC Close Date & Time

10 AUG 2020 17:23

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

10 AUG 2020 18:18

PC Close Date & Time

11 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

11 AUG 2020 18:22

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:01

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 18:49

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:16

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

96.7 °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

15 AUG 2020 17:29

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:29

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

10 AUG 2020 15:05

PC Open Date & Time

10 AUG 2020 14:53

PC Close Date & Time

10 AUG 2020 17:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

10 AUG 2020 18:18

PC Close Date & Time

11 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

11 AUG 2020 18:23

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

12 AUG 2020 18:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

13 AUG 2020 18:50

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

14 AUG 2020 18:19

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

15 AUG 2020 17:29

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

16 AUG 2020 22:29

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:06
PC Open Date & Time	10 AUG 2020 14:53
PC Close Date & Time	10 AUG 2020 17:23

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 18:18

PC Close Date & Time

11 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	11 AUG 2020 18:24
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

62 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	12 AUG 2020 18:02
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

64 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	13 AUG 2020 18:51
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

66 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	14 AUG 2020 18:20
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

68 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	15 AUG 2020 17:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

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)

70 of 2872

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	16 AUG 2020 22:30
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3222068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	VISIT2

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:51
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 14:51
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 14:20

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

US3222068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	14:03 (24 HR)
Collection date and time (derived)	9 SEP 2020 14:03

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:08	9 SEP 2020 14:08
Nasopharyngeal Swab 2	No		

US3222068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 14:47

PC Open Date & Time

09 SEP 2020 14:40

PC Close Date & Time

09 SEP 2020 17:10

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	09 SEP 2020 19:57
PC Open Date & Time	09 SEP 2020 18:05
PC Close Date & Time	10 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:58

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 22:45

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

97.8 °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

13 SEP 2020 15:23

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

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

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 14:48

PC Open Date & Time

09 SEP 2020 14:40

PC Close Date & Time

09 SEP 2020 17:10

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

09 SEP 2020 19:58

PC Open Date & Time

09 SEP 2020 18:05

PC Close Date & Time

10 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

11 SEP 2020 15:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

12 SEP 2020 22:45

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

13 SEP 2020 15:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

14 SEP 2020 18:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 ☐

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

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 14:49
PC Open Date & Time	09 SEP 2020 14:40
PC Close Date & Time	09 SEP 2020 17:10

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 19:58
PC Open Date & Time	09 SEP 2020 18:05
PC Close Date & Time	10 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

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)

108 of 2872

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	11 SEP 2020 16:00
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

EAB) (1725)

110 of 2872

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	12 SEP 2020 22:46
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

112 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	13 SEP 2020 15:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

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)

114 of 2872

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

Yes ☐	
PC Time stamp	14 SEP 2020 18:06
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

116 of 2872

EAB) (1725)

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments 2 ATTEMPTS MADE TO
CONTACT PATIENT. 30 SEP 2020
LEFT MESSAGE FOR PATIENT
TO RETURN CALL. 1 OCT 2020
CALLED AND LEFT MESSAGE
FOR SAFETY CALL.

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:35:26

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:35:26

Generated On: 09 Jun 2021 16:05:47

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) _____

US3222068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

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.

US3222068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

12:50 (24 HR)

Collection date and time (derived)

7 OCT 2020 12:50

US3222068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:18

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 09:38:11

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 14:20:27

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 12:31:48

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

07 NOV 2020 11:41:38

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

14 NOV 2020 13:54:57

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

19 NOV 2020 20:15:58

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☒

Yes ☐

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

25 NOV 2020 08:28:35

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 08:52:32

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

09 DEC 2020 22:29:03

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 15:36:03

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

23 DEC 2020 07:46:17

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

30 DEC 2020 13:50:25

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 19:12:40

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 09:52:11

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 10:05:47

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☒

Yes ☐

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

19 FEB 2021 11:56:45

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 FEB 2021 16:01:15
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 17:48:22

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

14 MAR 2021 09:43:59

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 12:14:52

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 20:28:42
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

07 APR 2021 17:28:42

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

Date and time of submission

21 APR 2021 17:55:00

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 341

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

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

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

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

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

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

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

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29 AUG 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New 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.

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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12 SEP 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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19 SEP 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 488

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

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

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

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

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

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

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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23 JAN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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06 FEB 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

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13 FEB 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

US3222068

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

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03 APR 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

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10 APR 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 614

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

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

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

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

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

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

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 ☐

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US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 621

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

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

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

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

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

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

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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20 APR 2022 00:01

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24 APR 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

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

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

US3222068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 18:00:58

US3222068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

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) _____

US3222068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

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.

US3222068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	04 MAR 2021 10:45

US3222068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222068

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:47

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3222068

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:05:47

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222068

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	24 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3222068

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Date of updated informed consent (dd MMM yyyy)	24 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (dd MMM yyyy)	24 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3222068

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Height	
Weight	
BMI (xxx.x)	

US3222068

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 JAN 2021
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	24 JAN 2021 10:47
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	24 JAN 2021 11:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 JAN 2021

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

US3222068

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

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) 24 JAN 2021

What was the treatment time? (00:00-23:59) 10:53 (24 HR)

Treatment Date and Time (derived) 24 JAN 2021 10:53

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

US3222068

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 JAN 2021

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

24 JAN 2021 10:25

US3222068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 JAN 2021

Collection time (00:00 - 23:59)

10:28

Collection Date and Time (derived)

24 JAN 2021 10:28

US3222068

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:35:17

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3222068

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 10:39
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 12:08
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3222068

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3222068

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

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) 04 MAR 2021

What was the treatment time? (00:00-23:59) 11:36 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 11:36

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

What was the frequency of the study treatment dosing? ONCE

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

US3222068

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222068

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

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) _____

US3222068

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

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.

US3222068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 APR 2021

Collection time (00:00-23:59)

10:00 (24 HR)

Collection date and time (derived)

1 APR 2021 10:00

US3222068

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:13:03

Generated On: 09 Jun 2021 16:05:47

AEID	USA-US104-2020-MRNA-1273-P30 1000008
Adverse event	ACUTE ON CHRONIC HYPOXIC RESPIRATORY FAILURE
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)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	5 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	5 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
PRODUCTION RELEASE (v12.003 EAB) (1725)	361 of 2872

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:13:03

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:13:03

Generated On: 09 Jun 2021 16:05:47

SUBJECT CALLED 911 FOR
CHEST PAIN ON 24/SEP/202.
ARRIVED AT ADVENT HEALTH
DAYTONA EMERGENCY ROOM
PRESENTED WITH SHORTNESS
OF BREATH AND CHEST PAIN
PRESENTING VITALS WERE:
1. TEMP 97.6 10/05/2020 14:42
2. O2 SAT 97% 10/010/05/2020
14:43
3. 5/2020 14:42 10/05/2020 14:42
4. RESP: 16 10/05/2020 14:42
5. B/P: 119/81 10/05/2020 14:43
6. A/O X 3

FINAL REPORT
VERIFIED
DATE/TIME/PERSONNEL:
10/3/2020 12:51 EDT (b) (6)
(b) (6) < 10,000 CFU/ML
CANDIDA ALBICANS WITH <
10,000 CFU/ML NORMAL
RESPIRATORY FLORA.
IN THE ER ABG PH 7.434, PCO2
42 P02 92 ON 2 L NASAL
CANNULA RESPIRATORY RATE
30 WBC 10 HEMOGLOBIN 11.3
PLATELETS 187 SODIUM 138
INR 1.4 POTASSIUM 4.5
CREATININE 0.9 TROPONINS
STENT PROBNP 41 NORMA LFTS
IACTIC ACID 1.7 COVID-19
NEGATIVE CT ANGIO
NEGATIVE FOR PE, BUT SHOWS
PROGRESSION OF THE

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:13:03

Generated On: 09 Jun 2021 16:05:47

PULMONARY FIBROSIS
ATELECTASIS BRONCHIECTASIS
HE WAS STARTED ON IV
ANTIBIOTICS, PULMONARY
CONSULTED, CARDIOLOGY
WAS CONSULTED HE WAS
PLACED BACK ON
METOPROLOL, DISCONTINUE
IMDUR AND ADDED RANEXA
PATIENT IMPROVED HIS
SLOWLY, HE COMPLAINS OF A
LOT OF SPUTUM PRODUCTION
MUCUS PLUG, PULMONARY
SCHEDULE HIM FOR
BRONCHOSCOPY PROCEDURE
DONE 10/01/2020 FINDINGS
CONSISTENT WITH MUCUS
PLUG HOWEVER (b) (6) IS
SICK OF THE PLAQUES WAS
SUGGESTIVE FOR ASPIRATION.
GL WAS CONSULTED AND SLP
CONSULTED AS WELL, HE
UNDERWENT MODIFIED
BARIUM SWALLOW SHOWS NO
ASPIRATION HOWEVER
PROVIDE RECOMMENDATIONS
PREVENT ASPIRATION, NO
INTERVENTION FROM GL,
FOLLOW-UP.

DISCHARGE DIAGNOSIS WAS
PNEUMONIA

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

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

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

Yes ☒

No ☐

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

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ALBUTEROL-IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 2.5-0.5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication CLONAZAPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication EDEMA - BILAT PEDAL EDEMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication RIVAROXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication DILTIAZAM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 120

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)

386 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ESBRIET - PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication PULMONRY FIBROSIS

Dose per administration 267

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)

388 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 200

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)

392 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication FUNGAL INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication 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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication SPIRONOLACTONE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 5 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ISOSORBIDE MONONITRATE

Prophylaxis Yes ☐
No ☒

Indication ANGINA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 5 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication ANGINA

Dose per administration 0.4

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

EVERY 5 MINUTES X 3
DOSES/PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication PIPERACILLIN-TAXOBACTAM

Prophylaxis Yes ☒
No ☐

Indication RESPIRATORY FAILURE.

Dose per administration 4.5

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☒
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		1 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐
No ☒

Indication COUGH

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

EVERY 4 HOURS FOR 5 DAYS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication ONDASTERONE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA AND VOMITING

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

IVP Q4H

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	5 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication POLYETHYLENE GLYCOL 3350

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication RANOLAZINE

Prophylaxis Yes ☐
No ☒

Indication ANGINA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

420 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	4 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 4 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	4 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

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

TAPER OVER 16 DAYS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication MULTI-VITAMIN WITH MINERALS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication SALMETEROL

Prophylaxis Yes ☐
No ☒

Indication PULMONARY FIBROSIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

Name of Medication	O2 THERAPY
Prophylaxis	Yes ☐
	No ☒

Indication	O2 NEEDED DURING PROCEDURE, BRONCHOLAVAGE

Dose per administration	4

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

If dose unit is Other, specify	LPM

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)

434 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 13:38:36

Generated On: 09 Jun 2021 16:05:47

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 15:35:16

Generated On: 09 Jun 2021 16:05:47

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 21:06:59

Generated On: 09 Jun 2021 16:05:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 SEP 2020	CT OF CHEST	Adverse Event	
24 OCT 2020	XR OF CHEST	Adverse Event	
1 OCT 2020	BRONCH LAVAGE RIGHT MIDDLE LOBE OF LUNG	Adverse Event	
2 OCT 2020	BARIUM SWALLOW	Adverse Event	
27 SEP 2020	XR CHEST	Adverse Event	
24 SEP 2020	ELECTRO CARDIO GRAM	Adverse Event	
25 SEP 2020	ARTERIAL BLOOD GAS	Adverse Event	
25 SEP 2020	NASAL CANNULA	Adverse Event	
25 SEP 2020	EMERGENCY BLOODWORK	Adverse Event	

US3222068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:47

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

US3222068

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:47

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 ☐

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/OCT/2020 17:26
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

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	20/OCT/2020 15:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/OCT/2020 14:46
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

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	26/OCT/2020 16:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	27/OCT/2020 08:25
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

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	05/NOV/2020 18:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/NOV/2020 10:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	05/MAR/2021 10:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Data signed: (b) (4) 25 Mar 2021 17:13:04

Generated On: 09 Jun 2021 16:05:47

SAEID	USA-US104-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:24
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

US3222068 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222068

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'US3222068'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:49:24

US3222068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:30:14

US3222068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:49:25

US3222068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Clinic (Clinic)'	Crystal Paccione (b) (4)	10 Aug 2020 19:30:14

US3222068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'SCRN'	System	10 Aug 2020 19:30:14

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:49:26

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '71'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'YEARS'	System	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '71'	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Male (M)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:30:55

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Aug 2020'	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2020'	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:49:25

US3222068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '1'	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:35:16

US3222068

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:31:27

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:58
Data point term sent to Coder	System	10 Aug 2020 19:34:30
User entered 'Allergic Rhinitis'	Crystal Paccione (b) (4)	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Sep 2019'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	10 Aug 2020 19:34:25
User entered 'No (N)'	Crystal Paccione (b) (4)	10 Aug 2020 19:33:58
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	10 Aug 2020 19:34:25
User entered empty; reason for change Data Entry Error	System	10 Aug 2020 19:34:25
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Crystal Paccione (b) (4)	10 Aug 2020 19:34:25
User entered '01 UNK 2010'	(b) (4)	10 Aug 2020 19:33:58
	System	10 Aug 2020 19:33:58
	Crystal Paccione (b) (4)	10 Aug 2020 19:33:58
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Sep 2019'	System	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2019'	System	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:34:25
User entered 'Jan 2010'	System	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:34:25
User entered '2010'	System	10 Aug 2020 19:33:58

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:11:58
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:14
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:59:04
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:50
Data point term sent to Coder	System	10 Aug 2020 19:35:34
User entered 'ATRIAL FIBRILLATION'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2015'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2015'	System	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2015'	System	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:35:04

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:00
Data point term sent to Coder	System	10 Aug 2020 19:35:35
User entered 'Back Surgery'	Crystal Paccione (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2010'	System	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2010'	System	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2010'	System	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2010'	System	10 Aug 2020 19:35:33

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:38
Data point term sent to Coder	System	10 Aug 2020 19:36:39
User entered 'Chronic back pain'	Crystal Paccione (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 1993'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 1993'	System	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '1993'	System	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:36:00

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:13:24
User closed query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:13:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:41:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:41:37
Data point term sent to Coder	System	10 Sep 2020 17:41:08
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:38
Coding entries removed.	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:31
User entered 'DIABETES MELLITUS TYPE II' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:31
Query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:23

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:59:54
User opened query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:59:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:03
Data point term sent to Coder	System	10 Aug 2020 19:37:40
User entered 'Diabetes Mellitus Type II'	Crystal Paccione (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2005'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2005'	System	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2005'	System	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:36:46

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Please review and update MH condition to reflect the type of Hernia Surgery (e.g. Inguinal hernia, Umbilical hernia, etc.). Please reconcile with the AE or CM eCRF as applicable, so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:14:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:02:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:02:38
Data point term sent to Coder	System	10 Sep 2020 17:26:20
Query 'Per DM CLR: Please review and update MH condition to reflect the type of Hernia Surgery (e.g. Inguinal hernia, Umbilical hernia, etc.). Please reconcile with the AE or CM eCRF as applicable, so there is an appropriate match. ' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:26:13
Coding entries removed.	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:26:07
User entered 'HERNIA SURGERY, UMBILICAL' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:26:07
User opened query 'Per DM CLR: Please review and update MH condition to reflect the type of Hernia Surgery (e.g. Inguinal hernia, Umbilical hernia, etc.). Please reconcile with the AE or CM eCRF as applicable, so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:00:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:45
Data point term sent to Coder	System	10 Aug 2020 19:37:41

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
User entered 'Hernia Surgery'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2004'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2004'	Crystal Paccione (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2004'	System	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2004'	System	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2004'	System	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2004'	System	10 Aug 2020 19:37:21

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:47
Data point term sent to Coder	System	10 Aug 2020 19:38:43
User entered 'Hypercholesterolemia'	Crystal Paccione (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2010'	System	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2010'	System	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:38:42

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:16:07
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:40:50
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:00:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	10 Aug 2020 19:39:46
User entered 'Hypertension'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2005'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2005'	System	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2005'	System	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:39:20

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:17:08
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:41:05
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:01:09
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:12
Data point term sent to Coder	System	10 Aug 2020 19:40:47
User entered 'Hypothyroidism'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2015'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2015'	System	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2015'	System	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:40:12

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:05:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:05:54
User closed query 'Per CDM: Thank for responding with bilateral. Please update the condition to include bilateral, rather than enter only in query response. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:24:24
Data point term sent to Coder	System	19 Oct 2020 19:21:25
Query 'Per CDM: Thank for responding with bilateral. Please update the condition to include bilateral, rather than enter only in query response. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:21:16
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 19:21:03
User entered 'KNEE REPLACEMENT - Bilat' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 19:21:03
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:09:28
User opened query 'Per CDM: Thank for responding with bilateral. Please update the condition to include bilateral, rather than enter only in query response. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:09:15
User closed query 'Per DM CLR: Please specify laterality of Knee Surgery (e.g. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:09:15

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'UNKNOWN' (Site from DM).	Amber Vasquez (b) (4)	10 Sep 2020 17:41:44
Query 'Per DM CLR: Please specify laterality of Knee Surgery (e.g. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment.	Amber Vasquez (b) (4)	10 Sep 2020 17:41:38
' answered with 'BILATERAL' (Site from DM).		
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:01:29
User opened query 'Per DM CLR: Please specify laterality of Knee Surgery (e.g. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment.	(b) (4), (b) (6)	10 Sep 2020 04:01:22
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	10 Aug 2020 19:41:49
User entered 'Knee replacement'	Crystal Paccione (b) (4)	10 Aug 2020 19:41:00
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2006'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2006'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2006'	System	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2006'	System	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2006'	System	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2006'	System	10 Aug 2020 19:41:00

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 14:06:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 14:06:29
Data point term sent to Coder	System	23 Oct 2020 14:05:50
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 14:05:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 14:05:28
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) PROSTATE CANCER 2) RAIDOTHERAPY TO PROSTRATE' (Site from System).	System	23 Oct 2020 14:05:02
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) PROSTATE CANCER 2) RAIDOTHERAPY TO PROSTRATE' answered with 'UPDATED' (Site from System).	Albert Garcia (b) (4)	23 Oct 2020 14:05:02
Data point term sent to Coder	System	23 Oct 2020 14:04:49
User entered 'PROSTATE CANCER' reason for change: Data Entry Error	Albert Garcia (b) (4)	23 Oct 2020 14:04:39
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) PROSTATE CANCER 2) RAIDOTHERAPY TO PROSTRATE' (Site from System).	Coder Import (b) (4)	08 Oct 2020 08:10:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

586 of 2872

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 19:42:50
User entered 'Prostate cancer- radiated cancer free now'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2010'	System	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2010'	System	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2010'	System	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2010'	System	10 Aug 2020 19:42:11

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Pulmonary fibrosis, LLT: Pulmonary fibrosis - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:25:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:25:12
Data point term sent to Coder	System	10 Aug 2020 19:43:52
User entered 'Plumonary Fibrosis'	Crystal Paccione (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Sep 2019'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Sep 2019'	System	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2019'	System	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:43:29

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Pedal edema - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 21:23:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 21:23:48
User closed query 'Per CDM: Location of Edema still needs to be updated, please reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:23:53
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 00:29:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 00:29:25
Query 'Per CDM: Location of Edema still needs to be updated, please reconcile. ' answered with 'Updated to reflect location of edema. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:23:56
Data point term sent to Coder	System	19 Oct 2020 19:23:28
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 19:22:45
User entered 'EDEMA - bilat pedal edema' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 19:22:45
User opened query 'Per CDM: Location of Edema still needs to be updated, please reconcile. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:15:29
User closed query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:15:29

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4)	10 Sep 2020 17:42:01
User opened query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	10 Sep 2020 04:01:53
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	11 Aug 2020 22:29:04
Data point term sent to Coder	System	10 Aug 2020 19:43:53
User entered 'Edema'	Crystal Paccione (b) (4)	10 Aug 2020 19:43:49
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Jan 2018'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Jan 2018'	System	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2018'	System	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	10 Aug 2020 19:43:49

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:29:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:29:26
Data point term sent to Coder	System	24 Oct 2020 10:28:30
User entered 'CODEINE ALLERGY'	douglas winter (b) (4)	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4)	
	douglas winter (b) (4)	24 Oct 2020 10:28:03
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	douglas winter (b) (4)	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4)	
	douglas winter (b) (4)	24 Oct 2020 10:28:03
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4)	
	douglas winter (b) (4)	24 Oct 2020 10:28:03
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:03
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	24 Oct 2020 10:27:40
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	23 Oct 2020 17:38:05

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 04:05:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 04:05:42
Data point term sent to Coder	System	24 Oct 2020 10:28:31
User entered 'GEMFIBROZIL ALLERGY'	douglas winter (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:28:29

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animal dander - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 04:05:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 04:05:41
Data point term sent to Coder	System	24 Oct 2020 10:29:31
User entered 'CAT DANDERE ALLERGY'	douglas winter (b) (4)	24 Oct 2020 10:29:26
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:29:26

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Grass allergy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:31:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:31:27
Data point term sent to Coder	System	24 Oct 2020 10:30:32
User entered 'GRASS ALLERGY'	douglas winter (b) (4)	24 Oct 2020 10:30:13
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:13

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Pollen allergy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:31:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 10:31:27
Data point term sent to Coder	System	24 Oct 2020 10:30:32
User entered 'POLLEN ALLERGY'	douglas winter (b) (4)	24 Oct 2020 10:30:29
	(b) (4)	

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	24 Oct 2020 10:30:29

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
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)	01 Dec 2020 14:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 14:06:51
Data point term sent to Coder	System	01 Dec 2020 14:05:45
User entered 'anxiety'	gail lavine (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '01 Sep 2019'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'Sep 2019'	System	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '2019'	System	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:05:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered empty.	System	01 Dec 2020 14:05:20

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '13:50'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered '10 Aug 2020 13:50'	System	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '167.6' cm	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
DataPoint set to visible.	(b) (4) System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '97.1' kg	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
DataPoint set to visible.	(b) (4) System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
Amendment Manager: User entered '34.56776'	System	16 Sep 2020 23:50:15
User entered '34.6'	System	10 Aug 2020 19:45:23
DataPoint set to visible.	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'kg/m2'	System	10 Aug 2020 19:45:23
DataPoint set to visible.	System	10 Aug 2020 18:35:32

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
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 17:35:18
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 21:09:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:40
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 13:07:36
User entered '36.7' C	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	15 Sep 2020 21:09:40
	(b) (4)	
User entered 'Oral (Oral)'	Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
	(b) (4)	

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:09:40
User entered '84'	Albert Garcia (b) (4)	15 Sep 2020 21:09:40
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
	(b) (4)	

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'bpm'	System	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:09:40
User entered '16'	Albert Garcia (b) (4)	15 Sep 2020 21:09:40
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
	(b) (4)	

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'breaths/min'	System	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:09:40
User entered '122'	Albert Garcia (b) (4)	15 Sep 2020 21:09:40
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
	(b) (4)	

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'mmHg'	System	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:09:40
User entered '88'	Albert Garcia (b) (4)	15 Sep 2020 21:09:40
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 19:45:23
	(b) (4)	

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User entered 'mmHg'	System	10 Aug 2020 19:45:23

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55

US3222068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55

US3222068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:45:38

US3222068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:19:02
Comment added 'DATES ARE CORRECT. PLEASE REMOVE QUERY'.	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:42:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 18:23:36
User entered '10 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:45:38

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Retired'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

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 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:30

US3222068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:41

US3222068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:41

US3222068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:36:41

US3222068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'VISIT1'	System	10 Aug 2020 18:36:41

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:27

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:20:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:20:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 18:19:27
User entered '185407' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:27

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:27

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:14

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:14

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:14

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:14

US3222068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:14

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:39
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:55
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:49

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
User entered '167.6' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:40
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:58
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:55

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
User entered '97.1' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:39
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:55
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:49

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
User entered '167.6' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:40
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:58
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:55

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
User entered '97.1' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '13:50'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '10 Aug 2020 13:50'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '36.7' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '84'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'bpm'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '16'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'breaths/min'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '122'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '88'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:39
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:55
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:33
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:49

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Height

Audit	User	Time (GMT)
User entered '167.6' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:40
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:09:57
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND'.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:18:29
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:21:58
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:50:38
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:30:40
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:11:55

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

Weight

Audit	User	Time (GMT)
User entered '97.1' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 08:13:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol correct' (Site from System).	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:35
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 19:48:19
User entered '15:04'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '10 Aug 2020 15:04'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '37.0' C	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 10:21:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 10:21:26
User entered '82' reason for change: Data Entry Error	Alicia Cevera (b) (4)	13 Aug 2020 10:21:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 19:48:19
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'bpm'	System	13 Aug 2020 10:21:26
User entered empty.	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '20'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'breaths/min'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '117'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '81'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Aug 2020 19:48:19

US3222068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:49:41

US3222068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:49:41

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:33'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '10 Aug 2020 14:33'	System	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'ONCE'	System	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:37:52

US3222068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:23

US3222068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:23

US3222068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:12'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:23

US3222068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '10 Aug 2020 14:12'	System	10 Aug 2020 19:50:23

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:15'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '10 Aug 2020 14:15'	System	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	10 Aug 2020 19:50:46

US3222068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:51

US3222068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	10 Aug 2020 19:50:51

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:04:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1d5e6d0a-f0c7-4cd4-a093-06d1899a620d'	System	10 Aug 2020 19:05:43
User entered 'Yes (Y)'	System	10 Aug 2020 19:05:43

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:04:51', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1d5e6d0a-f0c7-4cd4-a093-06d1899a620d' User entered '98.6'	System	10 Aug 2020 19:05:43
	System	10 Aug 2020 19:05:43

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:04:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1d5e6d0a-f0c7-4cd4-a093-06d1899a620d'	System	10 Aug 2020 19:05:43
User entered 'No (N)'	System	10 Aug 2020 19:05:43

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:05', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1d5e6d0a-f0c7-4cd4-a093-06d1899a620d'	System	10 Aug 2020 19:05:43
User entered '10 Aug 2020 15:05'	System	10 Aug 2020 19:05:43

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 14:53'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 17:23'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 18:18'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 2'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:22:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bfdac29-981e-45bc-908a-a0d56191cbee'	System	11 Aug 2020 22:23:32
User entered 'Yes (Y)'	System	11 Aug 2020 22:23:32

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:22:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bfdac29-981e-45bc-908a-a0d56191cbee' User entered '98.3'	System	11 Aug 2020 22:23:32
	System	11 Aug 2020 22:23:32

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:21:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bfdac29-981e-45bc-908a-a0d56191cbee'	System	11 Aug 2020 22:23:32
User entered 'No (N)'	System	11 Aug 2020 22:23:32

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:22:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bfdac29-981e-45bc-908a-a0d56191cbee'	System	11 Aug 2020 22:23:32
User entered '11 Aug 2020 18:22'	System	11 Aug 2020 22:23:32

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 3'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:00:19', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '736133b9-46ea-4673-bbc0-d2dd16015f4e'	System	12 Aug 2020 22:02:03
User entered 'Yes (Y)'	System	12 Aug 2020 22:02:03

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:10', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '736133b9-46ea-4673-bbc0-d2dd16015f4e' User entered '98.3'	System	12 Aug 2020 22:02:03
	System	12 Aug 2020 22:02:03

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:00:50', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '736133b9-46ea-4673-bbc0-d2dd16015f4e'	System	12 Aug 2020 22:02:03
User entered 'No (N)'	System	12 Aug 2020 22:02:03

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '736133b9-46ea-4673-bbc0-d2dd16015f4e'	System	12 Aug 2020 22:02:03
User entered '12 Aug 2020 18:01'	System	12 Aug 2020 22:02:03

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 4'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:49:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd89968b-057e-4071-9e72-f831fe1a6639'	System	13 Aug 2020 22:50:37
User entered 'Yes (Y)'	System	13 Aug 2020 22:50:37

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:49:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd89968b-057e-4071-9e72-f831fe1a6639'	System	13 Aug 2020 22:50:37
User entered '97.9'	System	13 Aug 2020 22:50:37

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:49:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd89968b-057e-4071-9e72-f831fe1a6639'	System	13 Aug 2020 22:50:37
User entered 'No (N)'	System	13 Aug 2020 22:50:37

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:49:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd89968b-057e-4071-9e72-f831fe1a6639'	System	13 Aug 2020 22:50:37
User entered '13 Aug 2020 18:49'	System	13 Aug 2020 22:50:37

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 5'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:16:29', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c83e3d06-12ad-4655-a3eb-b6e8aa6b89e4'	System	14 Aug 2020 22:17:34
User entered 'Yes (Y)'	System	14 Aug 2020 22:17:34

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:16:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c83e3d06-12ad-4655-a3eb-b6e8aa6b89e4' User entered '98.4'	System	14 Aug 2020 22:17:34
	System	14 Aug 2020 22:17:34

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:16:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c83e3d06-12ad-4655-a3eb-b6e8aa6b89e4'	System	14 Aug 2020 22:17:34
User entered 'No (N)'	System	14 Aug 2020 22:17:34

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:16:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c83e3d06-12ad-4655-a3eb-b6e8aa6b89e4'	System	14 Aug 2020 22:17:34
User entered '14 Aug 2020 18:16'	System	14 Aug 2020 22:17:34

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 6'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:01', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '09db2d9b-0b8b-49ec-be2c-a554f116f2d5'	System	15 Aug 2020 21:30:09
User entered 'Yes (Y)'	System	15 Aug 2020 21:30:09

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '09db2d9b-0b8b-49ec-be2c-a554f116f2d5'	System	15 Aug 2020 21:30:09
User entered '96.7'	System	15 Aug 2020 21:30:09

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:21', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '09db2d9b-0b8b-49ec-be2c-a554f116f2d5'	System	15 Aug 2020 21:30:09
User entered 'No (N)'	System	15 Aug 2020 21:30:09

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:27', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '09db2d9b-0b8b-49ec-be2c-a554f116f2d5'	System	15 Aug 2020 21:30:09
User entered '15 Aug 2020 17:29'	System	15 Aug 2020 21:30:09

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 7'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:28:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd2b9b41-7395-4822-b162-7723b6fd9b1c'	System	17 Aug 2020 02:29:54
User entered 'Yes (Y)'	System	17 Aug 2020 02:29:54

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:01', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd2b9b41-7395-4822-b162-7723b6fd9b1c'	System	17 Aug 2020 02:29:54
User entered '98.4'	System	17 Aug 2020 02:29:54

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd2b9b41-7395-4822-b162-7723b6fd9b1c'	System	17 Aug 2020 02:29:54
User entered 'No (N)'	System	17 Aug 2020 02:29:54

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd2b9b41-7395-4822-b162-7723b6fd9b1c'	System	17 Aug 2020 02:29:54
User entered '16 Aug 2020 22:29'	System	17 Aug 2020 02:29:54

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '78613882-e965-4df3-a706-34d53b59a307'	System	10 Aug 2020 19:06:18
User entered 'None (1)'	System	10 Aug 2020 19:06:18

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '78613882-e965-4df3-a706-34d53b59a307'	System	10 Aug 2020 19:06:18
User entered 'No (N)'	System	10 Aug 2020 19:06:18

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '78613882-e965-4df3-a706-34d53b59a307'	System	10 Aug 2020 19:06:18
User entered 'No (N)'	System	10 Aug 2020 19:06:18

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '78613882-e965-4df3-a706-34d53b59a307'	System	10 Aug 2020 19:06:18
User entered 'None (1)'	System	10 Aug 2020 19:06:18

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:40', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '78613882-e965-4df3-a706-34d53b59a307'	System	10 Aug 2020 19:06:18
User entered '10 Aug 2020 15:05'	System	10 Aug 2020 19:06:18

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 14:53'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 17:23'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 18:18'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 2'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:02', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35a48587-85c9-4864-bd01-352c60505da6'	System	11 Aug 2020 22:24:08
User entered 'None (1)'	System	11 Aug 2020 22:24:08

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:07', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35a48587-85c9-4864-bd01-352c60505da6'	System	11 Aug 2020 22:24:08
User entered 'No (N)'	System	11 Aug 2020 22:24:08

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35a48587-85c9-4864-bd01-352c60505da6'	System	11 Aug 2020 22:24:08
User entered 'No (N)'	System	11 Aug 2020 22:24:08

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35a48587-85c9-4864-bd01-352c60505da6'	System	11 Aug 2020 22:24:08
User entered 'None (1)'	System	11 Aug 2020 22:24:08

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:30', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35a48587-85c9-4864-bd01-352c60505da6'	System	11 Aug 2020 22:24:08
User entered '11 Aug 2020 18:23'	System	11 Aug 2020 22:24:08

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 3'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1c35f2a1-0d0f-41ab-bfb4-9797faed62db'	System	12 Aug 2020 22:02:40
User entered 'None (1)'	System	12 Aug 2020 22:02:40

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1c35f2a1-0d0f-41ab-bfb4-9797faed62db'	System	12 Aug 2020 22:02:40
User entered 'No (N)'	System	12 Aug 2020 22:02:40

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1c35f2a1-0d0f-41ab-bfb4-9797faed62db'	System	12 Aug 2020 22:02:40
User entered 'No (N)'	System	12 Aug 2020 22:02:40

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:01:48', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1c35f2a1-0d0f-41ab-bfb4-9797faed62db'	System	12 Aug 2020 22:02:40
User entered 'None (1)'	System	12 Aug 2020 22:02:40

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:02', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1c35f2a1-0d0f-41ab-bfb4-9797faed62db'	System	12 Aug 2020 22:02:40
User entered '12 Aug 2020 18:02'	System	12 Aug 2020 22:02:40

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 4'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:14', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '452e4264-8654-4bf9-8886-1e5de4a8f1f3'	System	13 Aug 2020 22:51:20
User entered 'None (1)'	System	13 Aug 2020 22:51:20

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:20', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '452e4264-8654-4bf9-8886-1e5de4a8f1f3'	System	13 Aug 2020 22:51:20
User entered 'No (N)'	System	13 Aug 2020 22:51:20

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:24', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '452e4264-8654-4bf9-8886-1e5de4a8f1f3'	System	13 Aug 2020 22:51:20
User entered 'No (N)'	System	13 Aug 2020 22:51:20

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '452e4264-8654-4bf9-8886-1e5de4a8f1f3'	System	13 Aug 2020 22:51:20
User entered 'None (1)'	System	13 Aug 2020 22:51:20

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '452e4264-8654-4bf9-8886-1e5de4a8f1f3'	System	13 Aug 2020 22:51:20
User entered '13 Aug 2020 18:50'	System	13 Aug 2020 22:51:20

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 5'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:17:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '73a5e754-6ace-48ab-81fa-f6afbb5971d9'	System	14 Aug 2020 22:20:04
User entered 'None (1)'	System	14 Aug 2020 22:20:04

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '73a5e754-6ace-48ab-81fa-f6afbb5971d9'	System	14 Aug 2020 22:20:04
User entered 'No (N)'	System	14 Aug 2020 22:20:04

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '73a5e754-6ace-48ab-81fa-f6afbb5971d9'	System	14 Aug 2020 22:20:04
User entered 'No (N)'	System	14 Aug 2020 22:20:04

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '73a5e754-6ace-48ab-81fa-f6afbb5971d9'	System	14 Aug 2020 22:20:04
User entered 'None (1)'	System	14 Aug 2020 22:20:04

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '73a5e754-6ace-48ab-81fa-f6afbb5971d9'	System	14 Aug 2020 22:20:04
User entered '14 Aug 2020 18:19'	System	14 Aug 2020 22:20:04

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 6'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '728d5b89-f723-4dea-aa0e-aab97733f25a'	System	15 Aug 2020 21:30:42
User entered 'None (1)'	System	15 Aug 2020 21:30:42

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '728d5b89-f723-4dea-aa0e-aab97733f25a'	System	15 Aug 2020 21:30:42
User entered 'No (N)'	System	15 Aug 2020 21:30:42

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:47', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '728d5b89-f723-4dea-aa0e-aab97733f25a'	System	15 Aug 2020 21:30:42
User entered 'No (N)'	System	15 Aug 2020 21:30:42

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:53', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '728d5b89-f723-4dea-aa0e-aab97733f25a'	System	15 Aug 2020 21:30:42
User entered 'None (1)'	System	15 Aug 2020 21:30:42

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:29:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '728d5b89-f723-4dea-aa0e-aab97733f25a'	System	15 Aug 2020 21:30:42
User entered '15 Aug 2020 17:29'	System	15 Aug 2020 21:30:42

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 7'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:21', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '8b8546ad-4015-44cc-81fb-cb5cd3b270a8'	System	17 Aug 2020 02:30:23
User entered 'None (1)'	System	17 Aug 2020 02:30:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '8b8546ad-4015-44cc-81fb-cb5cd3b270a8'	System	17 Aug 2020 02:30:23
User entered 'No (N)'	System	17 Aug 2020 02:30:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:30', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '8b8546ad-4015-44cc-81fb-cb5cd3b270a8'	System	17 Aug 2020 02:30:23
User entered 'No (N)'	System	17 Aug 2020 02:30:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '8b8546ad-4015-44cc-81fb-cb5cd3b270a8'	System	17 Aug 2020 02:30:23
User entered 'None (1)'	System	17 Aug 2020 02:30:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:40', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '8b8546ad-4015-44cc-81fb-cb5cd3b270a8'	System	17 Aug 2020 02:30:23
User entered '16 Aug 2020 22:29'	System	17 Aug 2020 02:30:23

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:49', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:05:56', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:01', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:08', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:13', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:16', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'None (0)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:24', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered 'No (N)'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-10T15:06:31', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd4e543fd-ea29-46e6-b29b-c741761411c6'	System	10 Aug 2020 19:07:10
User entered '10 Aug 2020 15:06'	System	10 Aug 2020 19:07:10

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 14:53'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 17:23'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Aug 2020 18:18'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 2'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:43', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:50', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:23:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:24:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'None (0)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:24:14', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered 'No (N)'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-11T18:24:23', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '50205bdd-dd9c-4d06-990e-c538d6b23044'	System	11 Aug 2020 22:25:02
User entered '11 Aug 2020 18:24'	System	11 Aug 2020 22:25:02

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 3'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:29', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'None (0)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:43', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered 'No (N)'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-12T18:02:47', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9f05edb4-bf89-4d01-a902-61329bf879dd'	System	12 Aug 2020 22:03:24
User entered '12 Aug 2020 18:02'	System	12 Aug 2020 22:03:24

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 4'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:50:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:04', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:10', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:15', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:21', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:28', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'None (0)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered 'No (N)'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-13T18:51:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e39ff379-4448-46cd-8a5c-799150021308'	System	13 Aug 2020 22:52:21
User entered '13 Aug 2020 18:51'	System	13 Aug 2020 22:52:21

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 5'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:32', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:39', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:44', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:48', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:19:56', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'None (0)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:20:01', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered 'No (N)'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-14T18:20:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '415ff8fd-37f2-44db-9acb-d968834c809a'	System	14 Aug 2020 22:20:46
User entered '14 Aug 2020 18:20'	System	14 Aug 2020 22:20:46

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 6'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:08', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:15', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:20', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:31', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'None (0)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered 'No (N)'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-15T17:30:50', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '438b6b16-5c77-4758-b873-a9478d88dac7'	System	15 Aug 2020 21:31:31
User entered '15 Aug 2020 17:30'	System	15 Aug 2020 21:31:31

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 7'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:48', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:29:59', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:04', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:09', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'None (0)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered 'No (N)'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-08-16T22:30:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '14639fac-f2a0-43eb-8c79-aa92e51def6a'	System	17 Aug 2020 02:31:09
User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:31:09

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:37:52

US3222068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	26 Aug 2020 14:23:06

US3222068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '17 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	26 Aug 2020 14:23:06

US3222068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4)	26 Aug 2020 14:23:06

US3222068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Amber Vasquez (b) (4)	26 Aug 2020 14:23:06

US3222068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	26 Aug 2020 14:23:13

US3222068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	26 Aug 2020 14:23:13

US3222068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	26 Aug 2020 14:23:36

US3222068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	26 Aug 2020 14:23:36

US3222068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4)	26 Aug 2020 14:23:36

US3222068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Amber Vasquez (b) (4)	26 Aug 2020 14:23:36

US3222068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	26 Aug 2020 14:23:52

US3222068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	26 Aug 2020 14:23:52

US3222068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	09 Sep 2020 18:23:18

US3222068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '31 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Sep 2020 18:23:18

US3222068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4)	09 Sep 2020 18:23:18

US3222068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Amber Vasquez (b) (4)	09 Sep 2020 18:23:18

US3222068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	09 Sep 2020 18:23:25

US3222068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	09 Sep 2020 18:23:25

US3222068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 7OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 07:48:27
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 7OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 14:11:20
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 7OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:16:15
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	09 Sep 2020 18:23:36

US3222068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Sep 2020 18:23:36

US3222068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Home (Home)'	Amber Vasquez (b) (4)	09 Sep 2020 18:23:36

US3222068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'VISIT2'	System	09 Sep 2020 18:23:36

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '13:51'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '9 Sep 2020 13:51'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '36.7' C	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '75'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'bpm'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '18'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'breaths/min'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '117'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '87'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:51'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '9 Sep 2020 14:51'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '36.7' C	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '72'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'bpm'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '16'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'breaths/min'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '106'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '78'	Albert Garcia (b) (4)	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'mmHg'	System	10 Sep 2020 16:32:54

US3222068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Sep 2020 16:33:06

US3222068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	Albert Garcia (b) (4)	10 Sep 2020 16:33:06

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Amber Vasquez (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Amber Vasquez (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:20'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '9 Sep 2020 14:20'	System	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'ONCE'	System	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 18:23:55

US3222068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Sep 2020 16:33:21

US3222068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	Albert Garcia (b) (4)	10 Sep 2020 16:33:21

US3222068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:03'	Albert Garcia (b) (4)	10 Sep 2020 16:33:21

US3222068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '9 Sep 2020 14:03'	System	10 Sep 2020 16:33:21

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '9 Sep 2020'	Albert Garcia (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '14:08'	Albert Garcia (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '9 Sep 2020 14:08'	System	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Albert Garcia (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	10 Sep 2020 16:34:14

US3222068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	09 Sep 2020 18:24:02

US3222068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	09 Sep 2020 18:24:02

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:47:15', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '23cc5d0c-2afd-433c-891b-ac59a52f127b'	System	09 Sep 2020 18:48:38
User entered 'Yes (Y)'	System	09 Sep 2020 18:48:38

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:47:27', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '23cc5d0c-2afd-433c-891b-ac59a52f127b' User entered '98.0'	System	09 Sep 2020 18:48:38
	System	09 Sep 2020 18:48:38

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:47:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '23cc5d0c-2afd-433c-891b-ac59a52f127b'	System	09 Sep 2020 18:48:38
User entered 'No (N)'	System	09 Sep 2020 18:48:38

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:47:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '23cc5d0c-2afd-433c-891b-ac59a52f127b'	System	09 Sep 2020 18:48:38
User entered '09 Sep 2020 14:47'	System	09 Sep 2020 18:48:38

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 14:40'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b5be94ba-f08b-4259-9107-e5d86775fa15'	System	09 Sep 2020 23:58:34
User entered 'Yes (Y)'	System	09 Sep 2020 23:58:34

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b5be94ba-f08b-4259-9107-e5d86775fa15' User entered '98.2'	System	09 Sep 2020 23:58:34
	System	09 Sep 2020 23:58:34

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:39', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b5be94ba-f08b-4259-9107-e5d86775fa15'	System	09 Sep 2020 23:58:34
User entered 'No (N)'	System	09 Sep 2020 23:58:34

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:43', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b5be94ba-f08b-4259-9107-e5d86775fa15' User entered '09 Sep 2020 19:57'	System	09 Sep 2020 23:58:34
	System	09 Sep 2020 23:58:34

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 18:05'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 2'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 3'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:58:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1cbcc730-3e1f-4c27-9752-2a56c28b6d92'	System	11 Sep 2020 19:59:29
User entered 'Yes (Y)'	System	11 Sep 2020 19:59:29

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:58:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1cbcc730-3e1f-4c27-9752-2a56c28b6d92'	System	11 Sep 2020 19:59:29
User entered '97.6'	System	11 Sep 2020 19:59:29

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:58:31', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1cbcc730-3e1f-4c27-9752-2a56c28b6d92'	System	11 Sep 2020 19:59:29
User entered 'No (N)'	System	11 Sep 2020 19:59:29

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:58:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1cbcc730-3e1f-4c27-9752-2a56c28b6d92'	System	11 Sep 2020 19:59:29
User entered '11 Sep 2020 15:58'	System	11 Sep 2020 19:59:29

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 4'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:44:55', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'efb925e9-7348-46b6-8c4c-c8d6a8cc8c03'	System	13 Sep 2020 02:46:17
User entered 'Yes (Y)'	System	13 Sep 2020 02:46:17

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:08', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'efb925e9-7348-46b6-8c4c-c8d6a8cc8c03'	System	13 Sep 2020 02:46:17
User entered '98.4'	System	13 Sep 2020 02:46:17

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:13', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'efb925e9-7348-46b6-8c4c-c8d6a8cc8c03'	System	13 Sep 2020 02:46:17
User entered 'No (N)'	System	13 Sep 2020 02:46:17

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:23', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'efb925e9-7348-46b6-8c4c-c8d6a8cc8c03'	System	13 Sep 2020 02:46:17
User entered '12 Sep 2020 22:45'	System	13 Sep 2020 02:46:17

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 5'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:23', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '117d6fce-9d79-47f1-b494-ac56ba793f38'	System	13 Sep 2020 19:24:37
User entered 'Yes (Y)'	System	13 Sep 2020 19:24:37

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '117d6fce-9d79-47f1-b494-ac56ba793f38'	System	13 Sep 2020 19:24:37
User entered '97.8'	System	13 Sep 2020 19:24:37

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:40', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '117d6fce-9d79-47f1-b494-ac56ba793f38'	System	13 Sep 2020 19:24:37
User entered 'No (N)'	System	13 Sep 2020 19:24:37

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:44', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '117d6fce-9d79-47f1-b494-ac56ba793f38'	System	13 Sep 2020 19:24:37
User entered '13 Sep 2020 15:23'	System	13 Sep 2020 19:24:37

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 6'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:04:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e0e8e46c-1afc-41e1-88ee-1ebcc509b84b'	System	14 Sep 2020 22:06:06
User entered 'Yes (Y)'	System	14 Sep 2020 22:06:06

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:04:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e0e8e46c-1afc-41e1-88ee-1ebcc509b84b'	System	14 Sep 2020 22:06:06
User entered '98.4'	System	14 Sep 2020 22:06:06

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:03', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e0e8e46c-1afc-41e1-88ee-1ebcc509b84b'	System	14 Sep 2020 22:06:06
User entered 'No (N)'	System	14 Sep 2020 22:06:06

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:08', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'e0e8e46c-1afc-41e1-88ee-1ebcc509b84b'	System	14 Sep 2020 22:06:06
User entered '14 Sep 2020 18:05'	System	14 Sep 2020 22:06:06

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 7'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:47:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9c4909cb-5a40-435e-8f3b-b1b324c04f9a'	System	09 Sep 2020 18:49:18
User entered 'None (1)'	System	09 Sep 2020 18:49:18

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:05', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9c4909cb-5a40-435e-8f3b-b1b324c04f9a'	System	09 Sep 2020 18:49:18
User entered 'No (N)'	System	09 Sep 2020 18:49:18

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:10', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9c4909cb-5a40-435e-8f3b-b1b324c04f9a'	System	09 Sep 2020 18:49:18
User entered 'No (N)'	System	09 Sep 2020 18:49:18

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:18', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9c4909cb-5a40-435e-8f3b-b1b324c04f9a'	System	09 Sep 2020 18:49:18
User entered 'None (1)'	System	09 Sep 2020 18:49:18

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9c4909cb-5a40-435e-8f3b-b1b324c04f9a'	System	09 Sep 2020 18:49:18
User entered '09 Sep 2020 14:48'	System	09 Sep 2020 18:49:18

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 14:40'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:49', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '5ed7022b-f9c2-49b4-a490-11aab1147d70'	System	09 Sep 2020 23:59:05
User entered 'None (1)'	System	09 Sep 2020 23:59:05

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '5ed7022b-f9c2-49b4-a490-11aab1147d70'	System	09 Sep 2020 23:59:05
User entered 'No (N)'	System	09 Sep 2020 23:59:05

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:57:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '5ed7022b-f9c2-49b4-a490-11aab1147d70'	System	09 Sep 2020 23:59:05
User entered 'No (N)'	System	09 Sep 2020 23:59:05

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:04', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '5ed7022b-f9c2-49b4-a490-11aab1147d70'	System	09 Sep 2020 23:59:05
User entered 'None (1)'	System	09 Sep 2020 23:59:05

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '5ed7022b-f9c2-49b4-a490-11aab1147d70'	System	09 Sep 2020 23:59:05
User entered '09 Sep 2020 19:58'	System	09 Sep 2020 23:59:05

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 18:05'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 2'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 3'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:05', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '93a88a0b-98a9-46d5-894b-0078eabc4b69'	System	11 Sep 2020 20:00:30
User entered 'None (1)'	System	11 Sep 2020 20:00:30

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:09', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '93a88a0b-98a9-46d5-894b-0078eabc4b69'	System	11 Sep 2020 20:00:30
User entered 'No (N)'	System	11 Sep 2020 20:00:30

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:14', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '93a88a0b-98a9-46d5-894b-0078eabc4b69'	System	11 Sep 2020 20:00:30
User entered 'No (N)'	System	11 Sep 2020 20:00:30

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:23', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '93a88a0b-98a9-46d5-894b-0078eabc4b69'	System	11 Sep 2020 20:00:30
User entered 'None (1)'	System	11 Sep 2020 20:00:30

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:36', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '93a88a0b-98a9-46d5-894b-0078eabc4b69'	System	11 Sep 2020 20:00:30
User entered '11 Sep 2020 15:59'	System	11 Sep 2020 20:00:30

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 4'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:29', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd98528e-561f-4c24-8e1d-faaa7d5bdd09'	System	13 Sep 2020 02:46:41
User entered 'None (1)'	System	13 Sep 2020 02:46:41

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd98528e-561f-4c24-8e1d-faaa7d5bdd09'	System	13 Sep 2020 02:46:41
User entered 'No (N)'	System	13 Sep 2020 02:46:41

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd98528e-561f-4c24-8e1d-faaa7d5bdd09'	System	13 Sep 2020 02:46:41
User entered 'No (N)'	System	13 Sep 2020 02:46:41

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd98528e-561f-4c24-8e1d-faaa7d5bdd09'	System	13 Sep 2020 02:46:41
User entered 'None (1)'	System	13 Sep 2020 02:46:41

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bd98528e-561f-4c24-8e1d-faaa7d5bdd09'	System	13 Sep 2020 02:46:41
User entered '12 Sep 2020 22:45'	System	13 Sep 2020 02:46:41

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 5'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:51', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1279aaa6-33da-4258-abe5-929defe024dd'	System	13 Sep 2020 19:25:01
User entered 'None (1)'	System	13 Sep 2020 19:25:01

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1279aaa6-33da-4258-abe5-929defe024dd'	System	13 Sep 2020 19:25:01
User entered 'No (N)'	System	13 Sep 2020 19:25:01

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:23:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1279aaa6-33da-4258-abe5-929defe024dd'	System	13 Sep 2020 19:25:01
User entered 'No (N)'	System	13 Sep 2020 19:25:01

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:02', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1279aaa6-33da-4258-abe5-929defe024dd'	System	13 Sep 2020 19:25:01
User entered 'None (1)'	System	13 Sep 2020 19:25:01

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:06', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '1279aaa6-33da-4258-abe5-929defe024dd'	System	13 Sep 2020 19:25:01
User entered '13 Sep 2020 15:24'	System	13 Sep 2020 19:25:01

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 6'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:15', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '86de9a39-8189-440e-b6de-93d060f99092'	System	14 Sep 2020 22:06:24
User entered 'None (1)'	System	14 Sep 2020 22:06:24

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:18', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '86de9a39-8189-440e-b6de-93d060f99092'	System	14 Sep 2020 22:06:24
User entered 'No (N)'	System	14 Sep 2020 22:06:24

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '86de9a39-8189-440e-b6de-93d060f99092'	System	14 Sep 2020 22:06:24
User entered 'No (N)'	System	14 Sep 2020 22:06:24

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '86de9a39-8189-440e-b6de-93d060f99092'	System	14 Sep 2020 22:06:24
User entered 'None (1)'	System	14 Sep 2020 22:06:24

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:30', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '86de9a39-8189-440e-b6de-93d060f99092'	System	14 Sep 2020 22:06:24
User entered '14 Sep 2020 18:05'	System	14 Sep 2020 22:06:24

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 7'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:43', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864' User entered 'None (0)'	System	09 Sep 2020 18:50:39
	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:48:56', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'None (0)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:02', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'None (0)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'None (0)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'None (0)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:29', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'None (0)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:40', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered 'No (N)'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T14:49:47', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'bebee65f-c381-40ad-9e27-ae82f7d41864'	System	09 Sep 2020 18:50:39
User entered '09 Sep 2020 14:49'	System	09 Sep 2020 18:50:39

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 14:40'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:22', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4'	System	09 Sep 2020 23:59:50
User entered 'None (0)'	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4'	System	09 Sep 2020 23:59:50
User entered 'None (0)'	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4'	System	09 Sep 2020 23:59:50
User entered 'None (0)'	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4' User entered 'None (0)'	System	09 Sep 2020 23:59:50
	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4' User entered 'None (0)'	System	09 Sep 2020 23:59:50
	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:45', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4'	System	09 Sep 2020 23:59:50
User entered 'None (0)'	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4'	System	09 Sep 2020 23:59:50
User entered 'No (N)'	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-09T19:58:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9bf17685-2764-4310-af44-dacb931d52e4' User entered '09 Sep 2020 19:58'	System	09 Sep 2020 23:59:50
	System	09 Sep 2020 23:59:50

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '09 Sep 2020 18:05'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 2'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 3'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'None (0)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:50', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'None (0)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'None (0)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T15:59:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f' User entered 'None (0)'	System	11 Sep 2020 20:01:11
	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T16:00:01', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'None (0)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T16:00:04', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'None (0)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T16:00:09', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered 'No (N)'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-11T16:00:13', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '2ca2ff0e-bfcf-441c-b072-7e49e9611d1f'	System	11 Sep 2020 20:01:11
User entered '11 Sep 2020 16:00'	System	11 Sep 2020 20:01:11

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 4'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f' User entered 'None (0)'	System	13 Sep 2020 02:47:14
	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:55', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered 'None (0)'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:45:59', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered 'None (0)'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:46:03', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered 'None (0)'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:46:07', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f' User entered 'None (0)'	System	13 Sep 2020 02:47:14
	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:46:10', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered 'None (0)'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:46:14', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered 'No (N)'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-12T22:46:18', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '07f1aef2-6d53-4e9b-afc3-494048beea0f'	System	13 Sep 2020 02:47:14
User entered '12 Sep 2020 22:46'	System	13 Sep 2020 02:47:14

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 5'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:13', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701' User entered 'None (0)'	System	13 Sep 2020 19:25:41
	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:20', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701' User entered 'None (0)'	System	13 Sep 2020 19:25:41
	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701'	System	13 Sep 2020 19:25:41
User entered 'None (0)'	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:29', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701' User entered 'None (0)'	System	13 Sep 2020 19:25:41
	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:33', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701' User entered 'None (0)'	System	13 Sep 2020 19:25:41
	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701' User entered 'None (0)'	System	13 Sep 2020 19:25:41
	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701'	System	13 Sep 2020 19:25:41
User entered 'No (N)'	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-13T15:24:46', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '553ff2ee-a1f9-4a0d-9032-c1fd15ad6701'	System	13 Sep 2020 19:25:41
User entered '13 Sep 2020 15:24'	System	13 Sep 2020 19:25:41

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 6'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:41', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:45', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:49', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:05:55', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'None (0)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:06:07', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered 'No (N)'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-09-14T18:06:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '6883e8c1-1d6a-4f21-86db-ff973ef9c8a8'	System	14 Sep 2020 22:07:08
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 22:07:08

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	09 Sep 2020 18:23:55
User entered 'Day 7'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

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 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:23:55

US3222068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:23:55

US3222068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:11:52

US3222068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '16 Sep 2020'	Albert Garcia (b) (4)	23 Oct 2020 14:11:52

US3222068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	23 Oct 2020 14:11:52

US3222068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:11:52

US3222068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:11:57

US3222068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	23 Oct 2020 14:11:57

US3222068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:13

US3222068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '23 Sep 2020'	Albert Garcia (b) (4)	23 Oct 2020 14:12:13

US3222068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:13

US3222068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:12:13

US3222068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:17

US3222068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	23 Oct 2020 14:12:17

US3222068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:30

US3222068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '30 Sep 2020'	Albert Garcia (b) (4)	23 Oct 2020 14:12:30

US3222068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	08 Nov 2020 14:02:30
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:30

US3222068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '2 attempts made to contact patient. 30 SEP 2020 left message for patient to return call. 1 OCT 2020 called and left message for safety call.' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:44:26
User entered 'Messages left with no contact' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	08 Nov 2020 14:02:30
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:12:30

US3222068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:12:35

US3222068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	23 Oct 2020 14:12:35

US3222068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:01

US3222068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered '7 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	23 Oct 2020 14:13:01

US3222068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:01

US3222068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered 'VISIT3'	System	23 Oct 2020 14:13:01

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered 'No (N)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:26
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered empty.	System	23 Oct 2020 14:13:06

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32

US3222068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32

US3222068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'No (N)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:10

US3222068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	Albert Garcia (b) (4)	23 Oct 2020 14:13:10

US3222068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:23

US3222068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '7 Oct 2020'	Albert Garcia (b) (4)	23 Oct 2020 14:13:23

US3222068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '12:50'	Albert Garcia (b) (4)	23 Oct 2020 14:13:23

US3222068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '7 Oct 2020 12:50'	System	23 Oct 2020 14:13:23

US3222068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Oct 2020 14:13:27

US3222068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	23 Oct 2020 14:13:27

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 64'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-11T09:37:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b6f59467-5cbf-4db1-9ba3-82f196aafb7a'	System	11 Oct 2020 13:39:13
User entered 'No (N)'	System	11 Oct 2020 13:39:13

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-11T09:38:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b6f59467-5cbf-4db1-9ba3-82f196aafb7a'	System	11 Oct 2020 13:39:13
User entered 'No (N)'	System	11 Oct 2020 13:39:13

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-11T09:38:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'b6f59467-5cbf-4db1-9ba3-82f196aafb7a'	System	11 Oct 2020 13:39:13
User entered '11 Oct 2020 09:38:11'	System	11 Oct 2020 13:39:13

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 71'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-21T14:19:50', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c465b16d-b946-4061-9063-4166c5f3a78c'	System	21 Oct 2020 18:21:34
User entered 'No (N)'	System	21 Oct 2020 18:21:34

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-21T14:20:21', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c465b16d-b946-4061-9063-4166c5f3a78c'	System	21 Oct 2020 18:21:34
User entered 'No (N)'	System	21 Oct 2020 18:21:34

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-21T14:20:27', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'c465b16d-b946-4061-9063-4166c5f3a78c' User entered '21 Oct 2020 14:20:27'	System	21 Oct 2020 18:21:34
	System	21 Oct 2020 18:21:34

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 78'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-24T12:31:37', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4054a487-1c01-4b07-ba82-6501e0cd7a08'	System	24 Oct 2020 16:32:54
User entered 'No (N)'	System	24 Oct 2020 16:32:54

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-24T12:31:43', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4054a487-1c01-4b07-ba82-6501e0cd7a08'	System	24 Oct 2020 16:32:54
User entered 'No (N)'	System	24 Oct 2020 16:32:54

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-10-24T12:31:48', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4054a487-1c01-4b07-ba82-6501e0cd7a08' User entered '24 Oct 2020 12:31:48'	System	24 Oct 2020 16:32:54
	System	24 Oct 2020 16:32:54

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 92'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-07T11:41:23', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '287420b3-eaf3-4519-ab6f-ed962ca8bc39'	System	07 Nov 2020 16:41:45
User entered 'No (N)'	System	07 Nov 2020 16:41:45

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-07T11:41:28', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '287420b3-eaf3-4519-ab6f-ed962ca8bc39'	System	07 Nov 2020 16:41:45
User entered 'No (N)'	System	07 Nov 2020 16:41:45

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-07T11:41:38', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '287420b3-eaf3-4519-ab6f-ed962ca8bc39' User entered '07 Nov 2020 11:41:38'	System	07 Nov 2020 16:41:45
	System	07 Nov 2020 16:41:45

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered 'Day 99'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-14T13:54:45', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9b64891d-7260-4167-aa90-6fc2a7ad34f2'	System	14 Nov 2020 18:55:05
User entered 'No (N)'	System	14 Nov 2020 18:55:05

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-14T13:54:51', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9b64891d-7260-4167-aa90-6fc2a7ad34f2'	System	14 Nov 2020 18:55:05
User entered 'No (N)'	System	14 Nov 2020 18:55:05

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-14T13:54:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9b64891d-7260-4167-aa90-6fc2a7ad34f2'	System	14 Nov 2020 18:55:05
User entered '14 Nov 2020 13:54:57'	System	14 Nov 2020 18:55:05

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:37:52

US3222068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:53
Data entry locked.	System	10 Aug 2020 18:37:52
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:37:52

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-11-19T20:15:47', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7fccea81-e081-492d-9e54-2451b5b92aa1'	System	20 Nov 2020 01:16:01
User entered 'No (N)'	System	20 Nov 2020 01:16:01

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-11-19T20:15:52', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7fccea81-e081-492d-9e54-2451b5b92aa1'	System	20 Nov 2020 01:16:01
User entered 'No (N)'	System	20 Nov 2020 01:16:01

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-19T20:15:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7fccea81-e081-492d-9e54-2451b5b92aa1'	System	20 Nov 2020 01:16:01
User entered '19 Nov 2020 20:15:58'	System	20 Nov 2020 01:16:01

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-11-25T08:28:20', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4672d9b1-b5cb-4a18-963b-61b3bdea0aa5'	System	25 Nov 2020 13:28:38
User entered 'No (N)'	System	25 Nov 2020 13:28:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-11-25T08:28:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4672d9b1-b5cb-4a18-963b-61b3bdea0aa5'	System	25 Nov 2020 13:28:38
User entered 'No (N)'	System	25 Nov 2020 13:28:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-11-25T08:28:35', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '4672d9b1-b5cb-4a18-963b-61b3bdea0aa5'	System	25 Nov 2020 13:28:38
User entered '25 Nov 2020 08:28:35'	System	25 Nov 2020 13:28:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-12-04T08:52:21', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35b5448c-4f6d-42e0-b8be-3c934c99a5f7'	System	04 Dec 2020 13:52:38
User entered 'No (N)'	System	04 Dec 2020 13:52:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-12-04T08:52:26', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35b5448c-4f6d-42e0-b8be-3c934c99a5f7'	System	04 Dec 2020 13:52:38
User entered 'No (N)'	System	04 Dec 2020 13:52:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-12-04T08:52:32', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '35b5448c-4f6d-42e0-b8be-3c934c99a5f7'	System	04 Dec 2020 13:52:38
User entered '04 Dec 2020 08:52:32'	System	04 Dec 2020 13:52:38

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-12-09T22:28:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '62259ff7-407c-4111-b97b-da66733680eb'	System	10 Dec 2020 03:29:10
User entered 'No (N)'	System	10 Dec 2020 03:29:10

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-12-09T22:28:57', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '62259ff7-407c-4111-b97b-da66733680eb'	System	10 Dec 2020 03:29:10
User entered 'No (N)'	System	10 Dec 2020 03:29:10

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-12-09T22:29:03', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '62259ff7-407c-4111-b97b-da66733680eb' User entered '09 Dec 2020 22:29:03'	System	10 Dec 2020 03:29:10
	System	10 Dec 2020 03:29:10

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-12-16T15:35:54', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'fcb9a4d4-02d1-430c-86e1-7a824d836f83'	System	16 Dec 2020 20:36:13
User entered 'No (N)'	System	16 Dec 2020 20:36:13

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-12-16T15:35:59', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'fcb9a4d4-02d1-430c-86e1-7a824d836f83'	System	16 Dec 2020 20:36:13
User entered 'No (N)'	System	16 Dec 2020 20:36:13

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-12-16T15:36:03', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'fcb9a4d4-02d1-430c-86e1-7a824d836f83' User entered '16 Dec 2020 15:36:03'	System	16 Dec 2020 20:36:13
	System	16 Dec 2020 20:36:13

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-12-23T07:45:58', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'abad80a9-2860-4c20-b13a-acaa41fc571e'	System	23 Dec 2020 12:46:22
User entered 'No (N)'	System	23 Dec 2020 12:46:22

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-12-23T07:46:12', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'abad80a9-2860-4c20-b13a-acaa41fc571e'	System	23 Dec 2020 12:46:22
User entered 'No (N)'	System	23 Dec 2020 12:46:22

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-12-23T07:46:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'abad80a9-2860-4c20-b13a-acaa41fc571e'	System	23 Dec 2020 12:46:22
User entered '23 Dec 2020 07:46:17'	System	23 Dec 2020 12:46:22

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2020-12-30T13:50:17', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '96e6118a-d8e5-4e69-b35a-350263033eaa'	System	30 Dec 2020 18:50:30
User entered 'No (N)'	System	30 Dec 2020 18:50:30

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2020-12-30T13:50:20', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '96e6118a-d8e5-4e69-b35a-350263033eaa'	System	30 Dec 2020 18:50:30
User entered 'No (N)'	System	30 Dec 2020 18:50:30

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2020-12-30T13:50:25', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '96e6118a-d8e5-4e69-b35a-350263033eaa'	System	30 Dec 2020 18:50:30
User entered '30 Dec 2020 13:50:25'	System	30 Dec 2020 18:50:30

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-01-06T19:12:31', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '46215b3e-10d6-46aa-a079-623d68458073'	System	07 Jan 2021 00:12:46
User entered 'No (N)'	System	07 Jan 2021 00:12:46

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-01-06T19:12:34', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '46215b3e-10d6-46aa-a079-623d68458073'	System	07 Jan 2021 00:12:46
User entered 'No (N)'	System	07 Jan 2021 00:12:46

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-01-06T19:12:40', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '46215b3e-10d6-46aa-a079-623d68458073'	System	07 Jan 2021 00:12:46
User entered '06 Jan 2021 19:12:40'	System	07 Jan 2021 00:12:46

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-01-13T09:52:04', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'afb5d54e-5998-4058-b89f-2bfba6ef2443'	System	13 Jan 2021 14:52:16
User entered 'No (N)'	System	13 Jan 2021 14:52:16

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-01-13T09:52:07', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'afb5d54e-5998-4058-b89f-2bfba6ef2443'	System	13 Jan 2021 14:52:16
User entered 'No (N)'	System	13 Jan 2021 14:52:16

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-01-13T09:52:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'afb5d54e-5998-4058-b89f-2bfba6ef2443'	System	13 Jan 2021 14:52:16
User entered '13 Jan 2021 09:52:11'	System	13 Jan 2021 14:52:16

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-01-20T10:05:39', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7ee7e480-5c14-46f8-acd8-cc0fc613cebf'	System	20 Jan 2021 15:05:53
User entered 'No (N)'	System	20 Jan 2021 15:05:53

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-01-20T10:05:42', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7ee7e480-5c14-46f8-acd8-cc0fc613cebf'	System	20 Jan 2021 15:05:53
User entered 'No (N)'	System	20 Jan 2021 15:05:53

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-01-20T10:05:47', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7ee7e480-5c14-46f8-acd8-cc0fc613cebf' User entered '20 Jan 2021 10:05:47'	System	20 Jan 2021 15:05:53

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-02-19T11:56:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9a9d38d1-6775-4bb5-a36e-830996749bec'	System	19 Feb 2021 19:33:42
User entered 'No (N)'	System	19 Feb 2021 19:33:42

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-02-19T11:56:11', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9a9d38d1-6775-4bb5-a36e-830996749bec'	System	19 Feb 2021 19:33:42
User entered 'No (N)'	System	19 Feb 2021 19:33:42

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-02-19T11:56:45', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '9a9d38d1-6775-4bb5-a36e-830996749bec'	System	19 Feb 2021 19:33:42
User entered '19 Feb 2021 11:56:45'	System	19 Feb 2021 19:33:42

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-02-26T16:00:55-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7cbe7381-d56a-43df-859b-8272d2f7540c' User entered 'No (N)'	System	26 Feb 2021 21:01:21
	System	26 Feb 2021 21:01:21

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-02-26T16:01:08-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7cbe7381-d56a-43df-859b-8272d2f7540c'	System	26 Feb 2021 21:01:21
User entered 'No (N)'	System	26 Feb 2021 21:01:21

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-02-26T16:01:15-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '7cbe7381-d56a-43df-859b-8272d2f7540c'	System	26 Feb 2021 21:01:21
User entered '26 Feb 2021 16:01:15'	System	26 Feb 2021 21:01:21

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-03-03T17:48:10-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dafd817e-abe4-4d0a-8beb-827e6e6a375e'	System	03 Mar 2021 22:48:26
User entered 'No (N)'	System	03 Mar 2021 22:48:26

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-03-03T17:48:17-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dafd817e-abe4-4d0a-8beb-827e6e6a375e'	System	03 Mar 2021 22:48:26
User entered 'No (N)'	System	03 Mar 2021 22:48:26

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-03T17:48:22-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dafd817e-abe4-4d0a-8beb-827e6e6a375e' User entered '03 Mar 2021 17:48:22'	System	03 Mar 2021 22:48:26
	System	03 Mar 2021 22:48:26

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-03-14T09:43:49-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'f33a88d9-77c4-418d-a127-9b179f9d123a'	System	14 Mar 2021 13:44:04
User entered 'No (N)'	System	14 Mar 2021 13:44:04

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-03-14T09:43:53-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'f33a88d9-77c4-418d-a127-9b179f9d123a'	System	14 Mar 2021 13:44:04
User entered 'No (N)'	System	14 Mar 2021 13:44:04

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-14T09:43:59-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'f33a88d9-77c4-418d-a127-9b179f9d123a' User entered '14 Mar 2021 09:43:59'	System	14 Mar 2021 13:44:04
	System	14 Mar 2021 13:44:04

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-03-18T12:14:43-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd2823624-b492-44fa-be57-193bfe901b42'	System	18 Mar 2021 16:18:06
User entered 'No (N)'	System	18 Mar 2021 16:18:06

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-03-18T12:14:48-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd2823624-b492-44fa-be57-193bfe901b42'	System	18 Mar 2021 16:18:06
User entered 'No (N)'	System	18 Mar 2021 16:18:06

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-18T12:14:52-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'd2823624-b492-44fa-be57-193bfe901b42'	System	18 Mar 2021 16:18:06
User entered '18 Mar 2021 12:14:52'	System	18 Mar 2021 16:18:06

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-03-24T20:28:31-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dc773916-a741-4d89-9f18-4e2b9992fcf5'	System	25 Mar 2021 00:29:05
User entered 'No (N)'	System	25 Mar 2021 00:29:05

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-03-24T20:28:37-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dc773916-a741-4d89-9f18-4e2b9992fcf5'	System	25 Mar 2021 00:29:05
User entered 'No (N)'	System	25 Mar 2021 00:29:05

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-24T20:28:42-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'dc773916-a741-4d89-9f18-4e2b9992fcf5' User entered '24 Mar 2021 20:28:42'	System	25 Mar 2021 00:29:05

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-04-07T17:28:32-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '13b1e1bf-f3a4-48d3-941a-d8bc5d2bb198' User entered 'No (N)'	System	07 Apr 2021 21:28:48

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-04-07T17:28:37-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '13b1e1bf-f3a4-48d3-941a-d8bc5d2bb198'	System	07 Apr 2021 21:28:48
User entered 'No (N)'	System	07 Apr 2021 21:28:48

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-04-07T17:28:42-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '13b1e1bf-f3a4-48d3-941a-d8bc5d2bb198'	System	07 Apr 2021 21:28:48
User entered '07 Apr 2021 17:28:42'	System	07 Apr 2021 21:28:48

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[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 (f95c146c4d15f1d9)', Time: '2021-04-21T17:54:41-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '57165d2b-de6d-4237-8460-3ef0e6af4198' User entered 'No (N)'	System	21 Apr 2021 21:55:14
	System	21 Apr 2021 21:55:14

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

Have you been exposed to someone with 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 (f95c146c4d15f1d9)', Time: '2021-04-21T17:54:46-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '57165d2b-de6d-4237-8460-3ef0e6af4198'	System	21 Apr 2021 21:55:14
User entered 'No (N)'	System	21 Apr 2021 21:55:14

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-04-21T17:55:00-04:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: '57165d2b-de6d-4237-8460-3ef0e6af4198' User entered '21 Apr 2021 17:55:00'	System	21 Apr 2021 21:55:14
	System	21 Apr 2021 21:55:14

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 02:53:37

US3222068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:53:37
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 02:53:37

US3222068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-02T18:00:33-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'ee77a76f-176d-45bd-a2d5-03b13fe3445a' User entered 'No (N)'	System	02 Mar 2021 23:02:48
	System	02 Mar 2021 23:02:48

US3222068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f95c146c4d15f1d9)', Time: '2021-03-02T18:00:58-05:00', User OID: 'PatientReportedOutcome (US3222068)', ODM File OID: 'ee77a76f-176d-45bd-a2d5-03b13fe3445a' User entered '02 Mar 2021 18:00:58'	System	02 Mar 2021 23:02:48
	System	02 Mar 2021 23:02:48

US3222068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 13:28:30

US3222068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '5 Nov 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 13:28:30

US3222068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 13:28:30

US3222068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) Alicia Cevera (b) (4)	19 Nov 2020 13:28:30

US3222068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 13:28:47

US3222068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:41:32
User entered '1'	System	19 Nov 2020 13:28:47

US3222068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:13:51

US3222068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) System	04 Jan 2021 20:16:04
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	04 Jan 2021 20:16:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Jan 2021 20:16:04
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:16:04
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Jan 2021 20:14:40
User entered '08 Dec 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:14:40
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Jan 2021 20:13:51
User entered '04 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 20:13:51

US3222068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:13:51

US3222068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:13:51

US3222068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 20:16:14
User entered 'Yes (Y)' reason for change: Data Entry Error	System	04 Jan 2021 20:16:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Jan 2021 20:16:14
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:16:10

US3222068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User entered '1'	System	04 Jan 2021 20:16:14
User entered empty.	System	04 Jan 2021 20:16:10

US3222068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:17:07

US3222068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:17:07

US3222068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:17:07

US3222068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:17:07

US3222068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:17:13

US3222068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User entered '1'	System	04 Jan 2021 20:17:13

US3222068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:09

US3222068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:09

US3222068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:09

US3222068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:09

US3222068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:12

US3222068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:41
User entered '1'	System	05 Mar 2021 15:59:12

US3222068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:23

US3222068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:23

US3222068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:23

US3222068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered 'VISIT4'	System	05 Mar 2021 15:59:23

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered empty.	System	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered empty.	System	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered empty.	System	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered empty.	System	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered empty.	System	31 Mar 2021 14:10:01

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10

US3222068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10

US3222068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:28

US3222068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:28

US3222068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:35

US3222068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:35

US3222068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10:45'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:35

US3222068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered '04 Mar 2021 10:45'	System	05 Mar 2021 15:59:35

US3222068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:59:39

US3222068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:29:10
User entered '1'	System	05 Mar 2021 15:59:39

US3222068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:04:01

US3222068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:04:01

US3222068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:04:01

US3222068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:04:01

US3222068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:04:08

US3222068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 13:04:08

US3222068

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:06

US3222068

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:06

US3222068

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:06

US3222068

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'UNBLND_DECIDE'	System	24 Jan 2021 17:56:06

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:33:41
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:37:17

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:14:51
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:33:46
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 12:33:41
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:14:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:37:17

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	24 Jan 2021 17:56:36

US3222068

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	24 Jan 2021 17:56:36

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered empty.	System	24 Jan 2021 18:08:51
DataPoint set to visible.	System	24 Jan 2021 17:56:36

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered empty.	System	24 Jan 2021 18:08:51
DataPoint set to visible.	System	24 Jan 2021 17:56:36

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Jan 2021 18:09:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Jan 2021 18:09:14
User entered '10:47' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 18:09:14
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Jan 2021 18:08:51
User entered empty.	(b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '24 Jan 2021 10:47'	System	24 Jan 2021 18:09:14
User entered empty.	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '73'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'bpm'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'breaths/min'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '130'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '90'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:47

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered empty.	System	24 Jan 2021 18:08:51
DataPoint set to visible.	System	24 Jan 2021 17:56:36

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Jan 2021 18:09:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Jan 2021 18:09:14
User entered '11:25' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 18:09:14
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Jan 2021 18:08:51
User entered empty.	(b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '24 Jan 2021 11:25'	System	24 Jan 2021 18:09:14
User entered empty.	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '70'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'bpm'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'breaths/min'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '124'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '86'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:08:51

US3222068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	24 Jan 2021 18:08:51

US3222068

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:53

US3222068

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:56:53

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mRNA-1273'	System	24 Jan 2021 17:59:56
DataPoint set to visible.	System	24 Jan 2021 17:56:36

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10:53'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '24 Jan 2021 10:53'	System	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'ONCE'	System	24 Jan 2021 17:59:56

US3222068

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'INTRAMUSCULAR'	System	24 Jan 2021 17:59:56

US3222068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'Subject ID: US3222068 Accession Number: 1F65195 Gender: Male YOB: 1949 Visit: OL-1 Drawdate: 24-Jan-2021 ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 06:50:07
Jennifer Dittman	(b) (4)	06 Mar 2021 14:05:39
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 19:53:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Jan 2021 18:01:03

US3222068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:03

US3222068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered '10:25'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:03

US3222068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '24 Jan 2021 10:25'	System	24 Jan 2021 18:01:03

US3222068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:13

US3222068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:47

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:13

US3222068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:47

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '10:28'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:13

US3222068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:47

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '24 Jan 2021 10:28'	System	24 Jan 2021 18:01:13

US3222068

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

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:01:19

US3222068

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

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	24 Jan 2021 18:01:19

US3222068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:51:58

US3222068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:51:58

US3222068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:51:58

US3222068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:51:58

US3222068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:52:01

US3222068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	03 Feb 2021 15:52:01

US3222068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	03 Feb 2021 15:52:01
DataPoint set to visible.	System	03 Feb 2021 15:52:01

US3222068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:54:11

US3222068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:54:11

US3222068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:54:11

US3222068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'OLD29'	System	05 Mar 2021 15:54:11

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10:39'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '04 Mar 2021 10:39'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '78'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'bpm'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'breaths/min'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '130'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '91'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '12:08'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '04 Mar 2021 12:08'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '76'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'bpm'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'breaths/min'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '118'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '85'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mmHg'	System	05 Mar 2021 15:55:31

US3222068

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:39

US3222068

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:39

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'mRNA-1273'	System	05 Mar 2021 15:55:55
DataPoint set to visible.	System	03 Feb 2021 15:52:01

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '11:36'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '04 Mar 2021 11:36'	System	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'ONCE'	System	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 15:55:55

US3222068

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:00

US3222068

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	05 Mar 2021 15:56:00

US3222068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:09:01

US3222068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:09:01

US3222068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:09:01

US3222068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:09:01

US3222068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:09:07

US3222068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:06:40
User entered '1'	System	11 Mar 2021 15:09:07

US3222068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:24

US3222068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:24

US3222068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[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 13:38:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:24

US3222068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 14:28:24

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 14:28:28

US3222068

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:33

US3222068

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:33

US3222068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:52

US3222068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:52

US3222068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
User entered '10:00'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:28:52

US3222068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 10:00'	System	01 Apr 2021 14:28:52

US3222068

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:45
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:50:59

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:21
User entered	System	08 Oct 2020 17:26:18
'USA-US104-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 17:26:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: AE indicates that there is a Chronic Hypoxic Respiratory Failure. However, there is no corresponding MH or prior AE record to match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 08:01:59
Query 'Per DM CLR: AE indicates that there is a Chronic Hypoxic Respiratory Failure. However, there is no corresponding MH or prior AE record to match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'per medical records see audit history' (Site from DM).	gail lavine (b) (4) (b) (4)	15 Jan 2021 14:45:50
User opened query 'Per DM CLR: AE indicates that there is a Chronic Hypoxic Respiratory Failure. However, there is no corresponding MH or prior AE record to match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:57:53
User closed query 'PV Query: Please consider updating SAE term to Acute on chronic hypoxic respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:41:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute on chronic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:13:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:13:21
Data point term sent to Coder	System	25 Nov 2020 15:12:59
Query 'PV Query: Please consider updating SAE term to Acute on chronic hypoxic respiratory failure.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	25 Nov 2020 15:12:28
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	25 Nov 2020 15:12:18
Coding entries removed.	douglas winter (b) (4) (b) (4)	25 Nov 2020 15:12:18
User entered 'Acute on chronic hypoxic respiratory failure' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	25 Nov 2020 15:12:18

PRODUCTION RELEASE (v12.003
EAB) (1725)

1974 of 2872

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating SAE term to Acute on chronic hypoxic respiratory failure.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:45:05
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:41:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 17:41:00
Data point term sent to Coder	System	26 Oct 2020 17:13:14
Coding entries removed.	douglas winter (b) (4)	26 Oct 2020 17:13:09
	(b) (4)	
User entered 'PNEUMONIA' reason for change: Data Entry Error	douglas winter (b) (4)	26 Oct 2020 17:13:09
	(b) (4)	
Comment added 'THIS PATIENT HAS SEVERAL NEW DIAGNOSIS SECONDARY TO AN SAE. DO I NEED TO ENTER EACH ONE OF THESE NEW DIAGNOSIS AS A SEPERATE AE OR KEEP THEM UNDER THE MAIN REASON FOR THE SAE?'	douglas winter (b) (4)	24 Oct 2020 10:53:15
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute on chronic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:33:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:33:36
Data point term sent to Coder	System	21 Oct 2020 21:54:06
Coding entries removed.	douglas winter (b) (4)	21 Oct 2020 21:53:47
	(b) (4)	
User entered 'Acute on chronic hypoxic respiratory faiiure' reason for change: Data Entry Error	douglas winter (b) (4)	21 Oct 2020 21:53:47
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:18:17

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:18:17
Data point term sent to Coder	System	08 Oct 2020 15:54:06
User entered 'PNEUMONIA LEFT SIDE'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'Yes (Y)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 12:00:16
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:58:28
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:58:19
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 19:01:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:48:42
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'No (N)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '24 Sep 2020'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
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	08 Oct 2020 15:53:57
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	08 Oct 2020 15:53:57
	(b) (4)	
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	08 Oct 2020 15:53:18
User entered '20:00'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:53:57
User entered '24 Sep 2020 20:00'	System	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '5 Oct 2020'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Oct 2020 15:54:14
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	08 Oct 2020 15:54:14
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Oct 2020 15:53:18
User entered '10:00'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:54:14
User entered '5 Oct 2020 10:00'	System	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
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	08 Oct 2020 15:53:57
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	08 Oct 2020 15:53:18
User entered 'Yes (Y)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Oct 2020 15:53:57
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).		08 Oct 2020 15:53:57
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	08 Oct 2020 15:53:57
	(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	08 Oct 2020 15:53:18
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '24 Sep 2020'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '5 Oct 2020'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'No (N)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User closed query 'PV Query: As the last dose of study drug was given on 09 Sep 2020 (prior to the event onset), please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:09:51
Query 'PV Query: As the last dose of study drug was given on 09 Sep 2020 (prior to the event onset), please update the action taken with study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:13:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 19:13:27
User opened query 'PV Query: As the last dose of study drug was given on 09 Sep 2020 (prior to the event onset), please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:11
User entered 'None (NONE)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 12:02:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED MEDICATION PAGES' (Site from DM).	douglas winter (b) (4) (b) (4)	04 Nov 2020 23:05:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:48:49
User entered '1'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User closed query 'Per CDM: Per previous query response "corrected"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' (Site from DM).	(b) (4)	16 Mar 2021 08:59:11
Query 'Per CDM: Per previous query response "corrected"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' answered with 'no CM procedure noted in records' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:36:01
Signature has been broken.	(b) (4), (b) (6)	15 Mar 2021 13:35:37
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:35:37
User opened query 'Per CDM: Per previous query response "corrected"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:34:03
User closed query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:34:03
Query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:03:03
User opened query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:46:26

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
DataPoint Un-verified.	Amber Vasquez (b) (4)	04 Mar 2021 14:03:40
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Amber Vasquez (b) (4)	04 Mar 2021 14:03:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4)	08 Oct 2020 15:53:18
	(b) (4)	

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:01:09
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates Progression of Atelectasis, Bronchiectasis and Pulmonary Fibrosis. However, there are no corresponding AE record that match the information. Please reconcile and update to record these events as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Mar 2021 12:27:42
	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Query 'Per DM CLR: Narrative indicates Progression of Atelectasis, Bronchiectasis and Pulmonary Fibrosis. However, there are no corresponding AE record that match the information. Please reconcile and update to record these events as appropriate. Otherwise, clarify.' answered with 'There was only 1 SAE , and narrative is a singular event in which the progression of all those events led to the pt.s pneumonia' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:51:11
User opened query 'Per DM CLR: Narrative indicates Progression of Atelectasis, Bronchiectasis and Pulmonary Fibrosis. However, there are no corresponding AE record that match the information. Please reconcile and update to record these events as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:03:25
User closed query 'Per DM CLR: SAE Narrative = DISCONTINUE IMDUR. However, please confirm if this medication was truly discontinued as this was noted to be "ongoing" on the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:25:43
User closed query 'Per DM CLR: SAE Narrative = WBC 10 HEMOGLOBIN 11.3 PLATELETS 187 SODIUM 138 INR 1.4 POTASSIUM 4.5 CREATININE 0.9 TROPONINS STENT PROBNP 41 NORMA LFTS IACTIC ACID 1.7. However, no Blood Work-UP is recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:24:22
User closed query 'Per DM CLR: SAE Narrative = ER ABG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:24:01

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = ON 2 L NASAL CANNULA. Please verify if this pertains to Oxygen supplementation. If yes, note that this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:23:51
Query 'Per DM CLR: SAE Narrative = DISCONTINUE IMDUR. However, please confirm if this medication was truly discontinued as this was noted to be "ongoing" on the CM eCRF. Please review and reconcile data as appropriate.' answered with 'end date entered in con meds' (Site from DM).	gail lavine (b) (4)	01 Dec 2020 14:01:41
Query 'Per DM CLR: SAE Narrative = WBC 10 HEMOGLOBIN 11.3 PLATELETS 187 SODIUM 138 INR 1.4 POTASSIUM 4.5 CREATININE 0.9 TROPONINS STENT PROBNP 41 NORMA LFTS IACTIC ACID 1.7. However, no Blood Work-UP is recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded as advised' (Site from DM).	gail lavine (b) (4)	01 Dec 2020 13:36:29
Query 'Per DM CLR: SAE Narrative = ON 2 L NASAL CANNULA. Please verify if this pertains to Oxygen supplementation. If yes, note that this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded as advised' (Site from DM).	gail lavine (b) (4)	01 Dec 2020 13:36:22
Query 'Per DM CLR: SAE Narrative = ER ABG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded as advised' (Site from DM).	gail lavine (b) (4)	01 Dec 2020 13:36:17
User opened query 'Per DM CLR: SAE Narrative = DISCONTINUE IMDUR. However, please confirm if this medication was truly discontinued as this was noted to be "ongoing" on the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:48:58

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = WBC 10 HEMOGLOBIN 11.3 PLATELETS 187 SODIUM 138 INR 1.4 POTASSIUM 4.5 CREATININE 0.9 TROPONINS STENT PROBNP 41 NORMA LFTS IACTIC ACID 1.7. However, no Blood Work-UP is recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:48:40
User opened query 'Per DM CLR: SAE Narrative = ON 2 L NASAL CANNULA. Please verify if this pertains to Oxygen supplementation. If yes, note that this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:48:31
User opened query 'Per DM CLR: SAE Narrative = ER ABG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:48:12
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)	05 Nov 2020 18:11:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 18:11:07
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 18:11:01

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
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 'ADDED TO NARRATIVE' (Site from Safety).	douglas winter (b) (4)	04 Nov 2020 23:27:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'ADDED TO NARRATIVE' (Site from Safety).	douglas winter (b) (4)	04 Nov 2020 23:27:44

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED 911 FOR CHEST PAIN ON 24/SEP/202. ARRIVED AT ADVENT HEALTH DAYTONA EMERGENCY ROOM PRESENTED WITH SHORTNESS OF BREATH AND CHEST PAIN PRESENTING VITALS WERE: 1. TEMP 97.6 10/05/2020 14:42 2. O2 SAT 97% 10/010/05/2020 14:43 3. 5/2020 14:42 10/05/2020 14:42 4. RESP: 16 10/05/2020 14:42 5. B/P: 119/81 10/05/2020 14:43 6. A/O X 3 FINAL REPORT VERIFIED DATE/TIME/PERSONNEL: 10/3/2020 12:51 EDT (b) (6) < 10,000 CFU/ML CANDIDA ALBICANS WITH < 10,000 CFU/ML NORMAL RESPIRATORY FLORA. In the ER ABG pH 7.434, pCO2 42 P02 92 on 2 L nasal cannula respiratory rate 30 WBC 10 hemoglobin 11.3 platelets 187 sodium 138 INR 1.4 potassium 4.5 creatinine 0.9 troponins stent proBNP 41 Norma LFTs iactic acid 1.7 COVID-19 negative CT angio negative for PE, but shows progression of the pulmonary fibrosis atelectasis bronchiectasi\$ he was started on IV antibiotics, pulmonary consulted, Cardiology was consuited he was placed back on metoproioi, discontinue Imdur and added Ranexa patient improved his siowiy, he complain of a lot of sputum production mucus plug, pulmonary schedule him for bronchoscopy procedure done 10/01/2020 findings consistent with mucus plug however (b) (6) is sick of the plaques was suggestive for aspiration. GI was consulted and SLP consulted as well, he underwent modified barium swallow shows no aspiration however provide recommendations prevent aspiration, no intervention from GI, follow-up. DISCHARGE DIAGNOSIS WAS PNEUMONIA' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Nov 2020 23:27:27

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'A REDACTED DISCHARGE SUMMARY WAS SENT' (Site from Safety). DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	04 Nov 2020 23:18:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:13:19
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 Nov 2020 19:01:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:54:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:54:20
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:54:02

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED 911 FOR CHEST PAIN ON 24/SEP/202. ARRIVED AT ADVENT HEALTH DAYTONA EMERGENCY ROOM PRESENTED WITH SHORTNESS OF BREATH AND CHEST PAIN PRESENTING VITALS WERE: 1. TEMP 97.6 10/05/2020 14:42 2. O2 SAT 97% 10/010/05/2020 14:43 3. 5/2020 14:42 10/05/2020 14:42 4. RESP: 16 10/05/2020 14:42 5. B/P: 119/81 10/05/2020 14:43 6. A/O X 3 Final Report Verified Date/Time/Personnel: 10/3/2020 12:51 EDT (b) (6) < 10,000 cfu/ml Candida albicans with < 10,000 cfu/ml Normal respiratory flora DISCHARGE DIAGNOSIS WAS PNEUMONIA' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	26 Oct 2020 17:14:23
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:38:06
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)	26 Oct 2020 16:38:03
User closed query 'PV Query: Please consider adding osteoarthritis noted as medical history on paper SAE form to the EDC.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:37:58
User closed query 'PV Query: Was a cause or organism of the pneumonia identified? If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:37:52
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:37:43

PRODUCTION RELEASE (v12.003
EAB) (1725)

2014 of 2872

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4)	23 Oct 2020 13:55:30
Query 'PV Query: Was a cause or organism of the pneumonia identified? If not, please state so.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4)	23 Oct 2020 13:55:13
Query 'PV Query: Please consider adding osteoarthritis noted as medical history on paper SAE form to the EDC.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4)	23 Oct 2020 13:54:40
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 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4)	23 Oct 2020 13:54:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4)	23 Oct 2020 13:53:52
User closed query 'PV Query: Presenting vitals were dated 05 Oct 2020 in the narrative. Please clarify if the vitals were taken on admission 24 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:45:47
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:45:45

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Presenting vitals were dated 05 Oct 2020 in the narrative. Please clarify if the vitals were taken on admission 24 Sep 2020?' answered with 'CORRECT 24/SEP/2020' (Site from Safety).	douglas winter (b) (4)	21 Oct 2020 21:50:57
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' answered with 'DATE 27/SEP/2020 TEST SARS COV2 COVID19 PCR NOT DETECTED' (Site from Safety).	douglas winter (b) (4)	21 Oct 2020 21:49:43
User entered 'SUBJECT CALLED 911 FOR CHEST PAIN ON 24/SEP/202. ARRIVED AT ADVENT HEALTH DAYTONA EMERGENCY ROOM PRESENTED WITH SHORTNESS OF BREATH AND CHEST PAIN PRESENTING VITALS WERE: 1. TEMP 97.6 10/05/2020 14:42 2. O2 SAT 97% 10/010/05/2020 14:43 3. 5/2020 14:42 10/05/2020 14:42 4. RESP: 16 10/05/2020 14:42 5. B/P: 119/81 10/05/2020 14:43 6. A/O X 3	douglas winter (b) (4)	21 Oct 2020 21:49:31
DISCHARGE DIAGNOSIS WAS PNEUMONIA' reason for change: Data Entry Error		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:51:06
User opened query 'PV Query: Was a cause or organism of the pneumonia identified? If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:53
User opened query 'PV Query: Please consider adding osteoarthritis noted as medical history on paper SAE form to the EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:45

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:27
User opened query 'PV Query: Presenting vitals were dated 05 Oct 2020 in the narrative. Please clarify if the vitals were taken on admission 24 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:20
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:50:02
User entered 'SUBJECT CALLED 911 FOR CHEST PAIN ON 24/SEP/202. ARRIVED AT ADVENT HEALTH DAYTONA EMERGENCY ROOM PRESENTED WITH SHORTNESS OF BREATH AND CHEST PAIN PRESENTING VITALS WERE: 1. TEMP 97.6 10/05/2020 14:42 2. O2 SAT 97% 10/010/05/2020 14:43 3. 5/2020 14:42 10/05/2020 14:42 4. RESP: 16 10/05/2020 14:42 5. B/P: 119/81 10/05/2020 14:43 6. A/O X 3 DISCHARGE DIAGNOSIS WAS PNEUMONIA REQUESTING MEDICAL RECORDS'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:53:18

US3222068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:47

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

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 15:53:18

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per ETRTR: SAE "Pneumonia Left Side" indicates Concomitant Medication was dosed. Please update ConMeds page as applicable, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 20:51:48
Query 'Per ETRTR: SAE "Pneumonia Left Side" indicates Concomitant Medication was dosed. Please update ConMeds page as applicable, thanks.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 14:01:08
User opened query 'Per ETRTR: SAE "Pneumonia Left Side" indicates Concomitant Medication was dosed. Please update ConMeds page as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 23:07:08
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:27:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:44:42
Data point term sent to Coder	System	24 Oct 2020 10:11:24
Coding entries removed.	douglas winter (b) (4)	24 Oct 2020 10:10:28
Coding entries removed.	douglas winter (b) (4)	24 Oct 2020 10:10:28
User entered 'ALBUTEROL-IPRATROPIUM' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:10:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:53:48
Data point term sent to Coder	System	10 Sep 2020 17:28:25
User entered 'ALBUTEROL'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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)	23 Oct 2020 14:22:59
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 15:58:13
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:58:03
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 07:32:29
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'SHORTNESS OF BREATH' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:10:28
	(b) (4)	
User entered 'ALLERGIC RHINITIS'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '2.5-0.5' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:10:28
	(b) (4)	
User entered '1'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:10:28
	(b) (4)	
User entered 'puff (PUFF)'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:24:37
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:10:28
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:28:34
User entered '01 Sep 2019' reason for change: Data Entry Error	Amber Vasquez (b) (4)	10 Sep 2020 17:28:34
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:28:22
User entered '01 Sep ' (non-conformant).	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:28:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:28:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:27:56
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'CONDITION DID NOT WORSEN. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:40:18
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:45:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 16:00:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 16:00:21
Data point term sent to Coder	System	12 Oct 2020 15:59:48
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:58:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:30:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

2040 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Sep 2020 17:30:47
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	10 Sep 2020 17:29:33
User entered 'ATORVASTATIN'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition of HYPERTENSION that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:23:09
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition of HYPERTENSION that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify.' answered with 'Updated to reflect as treatment for indication' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:15:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 19:14:58
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition of HYPERTENSION that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:57:05
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:57:05
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#9) 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 15:58:54
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:33:51
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:29:24

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'HYPERCHOLESTEROLEMIA'	Albert Garcia (b) (4)	12 Oct 2020 15:58:49
reason for change: Data Entry Error	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '40'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:23:52
	(b) (4)	
User entered '01 Jan 2010'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:29:24
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:29:24

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:29:24

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:29:24

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:30:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:30:47
Data point term sent to Coder	System	10 Sep 2020 17:30:35
User entered 'CLONAZAPAM'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:30:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query ""	(b) (4)	
Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH eCRF is updated to reflect this update. "	(b) (4), (b) (6)	13 Nov 2020 13:33:40
' (Site from DM).		
Query ""	Albert Garcia (b) (4)	12 Oct 2020 15:59:18
Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH eCRF is updated to reflect this update. "	(b) (4)	
' answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 15:59:14
User opened query ""	(b) (4)	
Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH eCRF is updated to reflect this update. "	(b) (4), (b) (6)	05 Oct 2020 07:32:14
' (Site from DM).		
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:52:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'added anxiety to medical history' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:06:15
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:39:46
User entered 'ANXIETY'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:30:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0.5'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 May 2020'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:30:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:30:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:30:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:30:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 19:20:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:20:30
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	19 Oct 2020 19:18:21 19 Oct 2020 19:17:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:32:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:32:51
Data point term sent to Coder User entered 'LASIX'	System Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:31:47 10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#14) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:22:42
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#14) 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 15:59:40
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:59:36
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#14) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:35:16
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per CDM : Please provide the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:22:44
Query 'Per CDM : Please provide the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Updated to reflect location of edema' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:17:54
User entered 'EDEMA - bilat pedal edema' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 19:17:31
User opened query 'Per CDM : Please provide the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:52:10
User entered 'EDEMA'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '20'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 Mar 2020'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:31:01
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:31:01

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:33:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:33:38
Data point term sent to Coder	System	10 Sep 2020 17:32:48
User entered 'LEVOTHYROXINE'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#10) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:34:25
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#10) 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 16:00:08
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:00:04
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#10) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:35:34
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'HYPOTHYROIDISM'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '100'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:34:29
User entered 'ug (ug)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:00:12
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:35:43
User entered 'Other (OTHER)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 16:00:04
	(b) (4)	
User entered 'MCQ'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:32:07
User entered '01 Jan 2015' reason for change: Data Entry Error	Amber Vasquez (b) (4)	10 Sep 2020 17:32:07
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:32:00
User entered '01 2015' (non-conformant).	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:00
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:32:00

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:33:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:33:38
Data point term sent to Coder	System	10 Sep 2020 17:32:49
User entered 'LISINOPRIL'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:34:48
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#9) 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 16:00:32
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:00:28
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:34:38
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'HYPERTENSION'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '5'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 Jan 2005'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:32:47
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:32:47

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:34:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:34:48
Data point term sent to Coder	System	10 Sep 2020 17:33:50
User entered 'METFORMIN'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:33:39

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#6) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:35:03
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#6) 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 16:00:50
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:00:46
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#6) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:33:28
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:33:39

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'DIABETES'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '500'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'twice daily (BID)'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 Jan 2005'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:33:39
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 17:33:39

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:33:39

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:33:39

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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)	10 Sep 2020 17:35:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:35:45
Data point term sent to Coder	System	10 Sep 2020 17:34:52
User entered 'METOPROLOL'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:34:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:35:20
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#9) 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 16:01:04
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:01:00
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:34:53
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:34:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '20'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 Jan 2010'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:34:19
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:34:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:34:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:34:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:36:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:36:39
Data point term sent to Coder	System	10 Sep 2020 17:35:55
User entered 'MORPHINE'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#5) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:35:36
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#5) 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 16:01:20
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:01:16
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#5) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:33:08
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'BACK PAIN'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '30'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'twice daily (BID)'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:35:19
User entered '01 Jan 2018' reason for change: Data Entry Error	Amber Vasquez (b) (4)	10 Sep 2020 17:35:19
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 17:35:05
User entered '-1 Jan 2018' (non-conformant).	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:35:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:35:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:38:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:38:50
Data point term sent to Coder	System	10 Sep 2020 17:38:03
User entered 'RIVAROXABAN'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:35:48
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#3) 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 16:01:45
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:01:40
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#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:32:54
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'ATRIAL FIBRILLATION'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '20'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '01 Jan 2015'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:37:22
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:37:22

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review if medications DILTIAZEM, FUROSEMIDE AND SPIRONOLACTONE were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:55:37
Query 'Per DM CLR: Please review if medications DILTIAZEM, FUROSEMIDE AND SPIRONOLACTONE were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'MEDICATIONS WORK IN CONJUNCTION WITH EACH OTHER AND WERE NOT ADDED DUE TO WORSENING CONDITION. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:42:22
User opened query 'Per DM CLR: Please review if medications DILTIAZEM, FUROSEMIDE AND SPIRONOLACTONE were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:54:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:26:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:26:57
Data point term sent to Coder	System	10 Sep 2020 17:39:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

2203 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'DILTIAZAM'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:38:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:35:58
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#9) 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 16:02:10
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:02:06
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#9) that matches this medication. If yes, please update 'Prophylaxis' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:34:18
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:38:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '120' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:05:09
	(b) (4)	
User entered '180'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'twice daily (BID)'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:22:57
	(b) (4)	
User entered '5 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:05:09
	(b) (4)	
User entered 'UN UNK 2017'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:38:14
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 17:38:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:38:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:38:14

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: PIRFENIDONE, PRODUCTSYNONYM: ESBRIET - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:38:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:38:27
Data point term sent to Coder	System	30 Mar 2021 17:44:24
Coding entries removed.	(b) (4), (b) (6)	30 Mar 2021 17:43:45
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: PIRFENIDONE, PRODUCTSYNONYM: ESBRIET - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:45:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:45:15
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.	(b) (4), (b) (6)	19 Feb 2021 11:24:43
' (Site from DM).		
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.	Albert Garcia (b) (4) (b) (4)	18 Feb 2021 15:32:59
' answered with 'UPDATED' (Site from DM).		
Data point term sent to Coder	System	18 Feb 2021 15:32:42
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	18 Feb 2021 15:32:33
User entered 'Esbriet - PROPIONATE' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Feb 2021 15:32:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

2222 of 2872

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:27:04
User closed query 'Per CDM: Per previous query response "UPDATED"; however, the correction is no obvious please provide location such as log line number/data field updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:13:05
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: OTHER ANTIINFECTIVES, PRODUCT: SODIUM PROPIONATE, PRODUCTSYNONYM: PROPIONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 14:27:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 14:27:03
Data point term sent to Coder	System	01 Dec 2020 14:26:04
Query 'Per CDM: Per previous query response "UPDATED"; however, the correction is not obvious please provide location such as log line number/data field updated. Thank you. ' answered with 'corrected' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:25:54
Coding entries removed.	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:25:36
User entered 'propionate' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:25:36
User opened query 'Per CDM: Per previous query response "UPDATED"; however, the correction is no obvious please provide location such as log line number/data field updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:29:43
User closed query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:29:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	12 Oct 2020 16:02:34
User opened query 'Per DM CLR: Please review if this is a combination drug, if so please update the medication name to include brand or name of each component. If not, please update the 'Dose' field to reflect only one dose. Update as appropriate' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:36:21
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: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:39:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:39:45
Data point term sent to Coder	System	10 Sep 2020 17:40:05
User entered 'FLUTICASONE'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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#13) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 09:44:20
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#13) 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 16:02:38
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:02:30
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#13) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:36:28
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'PULMONRY FIBROSIS'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:30:26
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'dose corrected' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:01:39
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 13:01:18
User entered '267' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 13:01:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:47:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '500' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 14:25:36
User entered '500/50'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:13:58
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'unit updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:05
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:29:36
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:11:14
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:44:08
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:02:42
User entered 'ug (ug)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 16:02:30
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:36:37
User entered 'Other (OTHER)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 16:02:30
	(b) (4)	
User entered 'MCG'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:02:00
User entered 'three times daily (TID)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 13:02:00
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'twice daily (BID)'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:38:36
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)	31 Mar 2021 10:11:27
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:44:03
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 17:43:45
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 17:43:45
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)	29 Mar 2021 03:33:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'UN Apr 2020'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 17:39:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 13:02:00
User entered '2'	System	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:39:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 21:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:25:36
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	04 Nov 2020 21:09:35 04 Nov 2020 21:08:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 10:13:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 10:13:30
Data point term sent to Coder User entered 'ASPIRIN'	System douglas winter (b) (4)	24 Oct 2020 10:12:24 24 Oct 2020 10:11:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per CDM: Please review the indication and update accordingly' (Site from DM).	(b) (4)	
Query 'Per CDM: Please review the indication and update accordingly' answered with 'UPDATED TERM' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 10:32:14
	douglas winter (b) (4)	04 Nov 2020 21:08:52
	(b) (4)	
User entered 'CARDIAC PROPHYLAXIS' reason for change: Data Entry Error	douglas winter (b) (4)	04 Nov 2020 21:08:38
	(b) (4)	
User opened query 'Per CDM: Please review the indication and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:40:11
User entered 'PROPHYLAXIS'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '81'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	24 Oct 2020 10:24:17
	(b) (4)	
User entered '5 Oct 2020'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Oct 2020 10:11:33
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:11:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:11:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 10:11:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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)	28 Dec 2020 14:46:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Dec 2020 14:46:20
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	28 Dec 2020 14:46:10 28 Dec 2020 14:45:33
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)	25 Oct 2020 04:04:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Oct 2020 04:04:41
Data point term sent to Coder	System	24 Oct 2020 10:15:25
User entered 'BENZONATATE'	douglas winter (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:28:34
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'THIS MEDICATION IS RELATED TO AFTERMATH OF SAE NOTED ON AE PAGE.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:46:35
User entered 'COUGH' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:45:33
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:48:14
User entered 'ANTITUSSIVE'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '200'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User entered '3'	System	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User entered '1'	System	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:05
User entered '804 (804)'	System	24 Oct 2020 10:14:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Oct 2020 10:17:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:17:30
Data point term sent to Coder	System	24 Oct 2020 10:16:25
User entered 'CHOLECALCIFEROL'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:16:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:16:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '1000'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'IU (IU)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '5 Oct 2020'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Oct 2020 10:16:15
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:16:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:16:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 10:16:15

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 10:21:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:21:32
Data point term sent to Coder	System	24 Oct 2020 10:20:26
User entered 'FLUCONAZOLE'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:03:16
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'THIS IS RELATED TO THE SAE NOTED IN THE AE CRF PAGE.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:47:48
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:59:32
User entered 'FUNGAL INFECTION'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '100'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '15 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User entered '1'	System	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User entered '1'	System	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:15:37
User entered '804 (804)'	System	24 Oct 2020 10:19:33

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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)	24 Oct 2020 10:23:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:23:34
Data point term sent to Coder	System	24 Oct 2020 10:22:26
User entered 'FUROSEMIDE'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:22:26

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'HYPERTENSION'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '20'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '25 Sep 2020'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Oct 2020 10:22:26
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:22:26

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 10:22:26

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 10:22:26

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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.	(b) (4) Coder Import (b) (4)	24 Oct 2020 10:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:27:35
Data point term sent to Coder	System	24 Oct 2020 10:26:27
User entered 'ACETAMINOPHEN'	douglas winter (b) (4) (b) (4)	24 Oct 2020 10:26:10

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'PAIN'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '650'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'as needed (PRN)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '24 Sep 2020'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Oct 2020 10:26:10
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 10:26:10

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 10:26:10

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 10:26:10

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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)	04 Nov 2020 21:20:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:20:28
Data point term sent to Coder	System	04 Nov 2020 21:04:28
User entered 'SPIRONOLACTONE'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '25'	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	04 Nov 2020 23:02:25
	(b) (4)	
User entered '24 Sep 2020'	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:04:27
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 21:04:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:10:17
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification.	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:48:36
' answered with 'MEDICATION WAS ADDED TO AID EXISITING MEDICATIONS. ' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:03:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:50:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:50:29
Data point term sent to Coder	System	04 Nov 2020 21:34:18
User entered 'HUMALOG'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'DIABETES TYPE 2'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per CDM: Per CCG only Numerical are expected to be recorded in this field. Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 10:56:16
Query 'Per CDM: Per CCG only Numerical are expected to be recorded in this field. Please review and update the data as appropriate,else clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 15:43:41
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 15:43:26
User opened query 'Per CDM: Per CCG only Numerical are expected to be recorded in this field. Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:10:38
User entered 'LOW DOSE'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'IU (IU)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'EVERY 4 HOURS'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	04 Nov 2020 23:04:32
User entered '24 Sep 2020'	(b) (4)	
	douglas winter (b) (4)	04 Nov 2020 21:33:38
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User entered empty.	System	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User entered empty.	System	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:34
User entered empty.	System	04 Nov 2020 21:33:38

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:36:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:36:30
Data point term sent to Coder	System	04 Nov 2020 21:36:21
User entered 'ISOSORBIDE MONONITRATE'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User closed query 'Per CDM: Thanks for your response however, there is currently no AE recorded for 'ANGINA' (start/stop; 24Sep2020;05Oct2020) on the AE eCRF? Please review and add all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	17 Mar 2021 09:54:32
' (Site from DM). Query 'Per CDM: Thanks for your response however, there is currently no AE recorded for 'ANGINA' (start/stop; 24Sep2020;05Oct2020) on the AE eCRF? Please review and add all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	16 Mar 2021 14:10:22
' answered with 'this was included in treatment for AE that was dated 24sep2020, that resolved on 05oct2020' (Site from DM). User opened query 'Per CDM: Thanks for your response however, there is currently no AE recorded for 'ANGINA' (start/stop; 24Sep2020;05Oct2020) on the AE eCRF? Please review and add all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	12 Mar 2021 14:11:30
' (Site from DM). User closed query 'Per CDM: Response noted, however Please provide MH# logline number that corresponds this Indication, else clarify.' (Site from DM). Query 'Per CDM: Response noted, however Please provide MH# logline number that corresponds this Indication, else clarify.' answered with 'This medication was started during AE 24Sep2020 and stopped 05Oct2020 and is documented in AE' (Site from DM). User opened query 'Per CDM: Response noted, however Please provide MH# logline number that corresponds this Indication, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 14:11:30
	(b) (4), (b) (6)	11 Mar 2021 14:13:52
	(b) (4), (b) (6)	09 Mar 2021 10:19:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:19:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Con med matches med hx no AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:44:19
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:28:11
User entered 'ANGINA'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '30'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '24 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Dec 2020 13:57:42
User entered 'Yes (Y)'	gail lavine (b) (4)	04 Nov 2020 21:35:55
	douglas winter (b) (4)	
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Dec 2020 13:57:59
User entered '5 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4)	01 Dec 2020 13:57:59
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Dec 2020 13:57:42
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:35:55
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User entered '1'	System	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User entered '1'	System	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:21:32
User entered '804 (804)'	System	04 Nov 2020 21:35:55

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:54:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:54:29
Data point term sent to Coder	System	04 Nov 2020 21:38:23
User entered 'NITROGLYCERIN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'ANGINA'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0.4'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'other (OTHER)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'EVERY 5 MINUTES X 3 DOSES/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Other (OTHER)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'SUBLINGUAL'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '24 Sep 2020'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	04 Nov 2020 21:38:12
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:12

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Dec 2020 15:49:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Dec 2020 15:49:48
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4)	01 Dec 2020 13:40:29 01 Dec 2020 13:40:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 05:07:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 05:07:56
Data point term sent to Coder	System	04 Nov 2020 22:12:11
User entered 'METHYLPREDNISOLONE'	douglas winter (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User closed query 'Per CDM RQ: Response noted, however this Indication does not match AE term, Please review and update the term which is reflecting in AE term at this Indication data field, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:59:07
Query 'Per CDM RQ: Response noted, however this Indication does not match AE term, Please review and update the term which is reflecting in AE term at this Indication data field, else clarify. ' answered with 'this was addressed in AE as pt was admitted and this was part of his treatment course' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:11:42
User opened query 'Per CDM RQ: Response noted, however this Indication does not match AE term, Please review and update the term which is reflecting in AE term at this Indication data field, else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:22:34
User closed query 'Per CDM: Response noted, however this Indication does not match AE term, Please review and reconcile, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:22:34
Query 'Per CDM: Response noted, however this Indication does not match AE term, Please review and reconcile, else clarify.' answered with 'Ae documented dates are 24sep2020-04Oct2020, medication was given within those dates' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:18:17
User opened query 'Per CDM: Response noted, however this Indication does not match AE term, Please review and reconcile, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:23:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:23:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'This con med corresponds to SAE of 24Sep2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:47:16
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:28:04
User closed query 'Per MM, please update indication if needed.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:23:57
Query 'Per MM, please update indication if needed.' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 13:41:14
User entered 'pneumonia' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	01 Dec 2020 13:40:03
User opened query 'Per MM, please update indication if needed.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:12:13
User entered 'STEROID'	douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '125'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'EVERY 6 HOURS'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '25 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User entered empty.	System	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User entered empty.	System	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:53
User entered empty.	System	04 Nov 2020 22:11:30

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 08:42:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 08:42:29
Data point term sent to Coder Coding entries removed.	System	28 Dec 2020 14:55:14
	Albert Garcia (b) (4)	28 Dec 2020 14:54:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 05:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 05:00:52
Data point term sent to Coder	System	04 Nov 2020 22:17:23
User entered 'PIPERACILLIN-TAXOBACTAM'	douglas winter (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:29:16
' (Site from DM).		
User entered 'RESPIRATORY FAILURE.' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:54:32
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:53:58
' answered with 'RELATED TO SAE NOTED ' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate	(b) (4), (b) (6)	23 Dec 2020 00:25:43
' (Site from DM).		
User entered 'ANTIBIOTIC'	douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4.5'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'g (g)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'EVERY 8 HOURS'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '25 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '1 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User entered empty.	System	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User entered empty.	System	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:22:06
User entered empty.	System	04 Nov 2020 22:16:19

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 12:12:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 12:12:17
Data point term sent to Coder	System	05 Nov 2020 12:11:37
User entered 'GUAIFENESIN'	douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:09:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'THIS IS RELATED TO THE NOTED SAE.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:55:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:03:37
User entered 'COUGH'	douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '100'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'EVERY 4 HOURS FOR 5 DAYS'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '05 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User entered empty.	System	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User entered empty.	System	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:16:35
User entered empty.	System	05 Nov 2020 12:10:53

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 14:43:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:43:22
Data point term sent to Coder	System	05 Nov 2020 13:53:20
User entered 'ONDASTERONE'	douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:28:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'RELATED TO NOTED SAE' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:55:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:25:06
User entered 'NAUSEA AND VOMITING'	douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'IVP Q4H'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '24 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User entered empty.	System	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User entered empty.	System	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:02
User entered empty.	System	05 Nov 2020 13:53:02

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
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: POLYETHYLENE GLYCOL 3350 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 15:23:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:23:21
Data point term sent to Coder	System	05 Nov 2020 15:22:57
User entered 'POLYETHYLENE GLYCOL 3350'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:29:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'RELATED TO SAE NOTED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:56:24
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:26:53
User entered 'CONSTIPATION'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '17'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'g (g)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '15 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User entered '1'	System	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User entered '1'	System	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:17:32
User entered '804 (804)'	System	05 Nov 2020 15:22:50

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: RANOLAZINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 15:26:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:26:19
Data point term sent to Coder User entered 'RANOLAZINE'	System douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:59 05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'ANGINA'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '500'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4 Nov 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User entered '2'	System	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User entered '1'	System	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:08
User entered '804 (804)'	System	05 Nov 2020 15:24:11

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 15:26:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:26:20
Data point term sent to Coder	System	05 Nov 2020 15:26:00
User entered 'LORAZEPAM'	douglas winter (b) (4)	05 Nov 2020 15:25:54
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query '5 OCT 2020 No 10 OCT 2020 No Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:24:33
' (Site from DM).		
Query '5 OCT 2020 No 10 OCT 2020 No Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:57:10
' answered with 'THIS IS RELATED TO NOTED SAE. PLEASE INDICATE HOW THIS SHOULD BE NOTED. ' (Site from DM).		
User opened query '5 OCT 2020 No 10 OCT 2020 No Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	22 Dec 2020 23:31:55
' (Site from DM).		
User entered 'ANXIETY'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0.5'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User entered '3'	System	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User entered '1'	System	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:20:17
User entered '804 (804)'	System	05 Nov 2020 15:25:54

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#8 METOPROLOL (01Jan2010-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:25:10
' (Site from DM).		
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#8 METOPROLOL (01Jan2010-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:57:42
' answered with 'DATES ARE ENTERED CORRECTLY.' (Site from DM).		
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#8 METOPROLOL (01Jan2010-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	22 Dec 2020 23:35:56
' (Site from DM).		
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.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:27:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:27:19
Data point term sent to Coder	System	05 Nov 2020 15:27:01
User entered 'METOPROLOL'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '25'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4 Nov 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User entered '2'	System	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User entered '1'	System	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:18:38
User entered '804 (804)'	System	05 Nov 2020 15:26:56

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 16:33:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:33:20
Data point term sent to Coder	System	05 Nov 2020 15:29:04
User entered 'PANTOPRAZOLE'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:28:46
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'RELATED TO SAE NOTED. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:58:55
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:25:22
User entered 'SUPPLEMENT'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '40'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4 Nov 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User entered '1'	System	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User entered '1'	System	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:15
User entered '804 (804)'	System	05 Nov 2020 15:28:27

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:39:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 15:39:19
Data point term sent to Coder	System	05 Nov 2020 15:38:28
User entered 'PREDNISONE'	douglas winter (b) (4)	05 Nov 2020 15:37:45
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'PNEUMONIA'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User closed query 'Per DM CLR: Please note that tapering doses should be reflected as separate entries in the CM page. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:06:30
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Query 'Per DM CLR: Please note that tapering doses should be reflected as separate entries in the CM page. Update as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:48:31
User opened query 'Per DM CLR: Please note that tapering doses should be reflected as separate entries in the CM page. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:30:31
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	05 Nov 2020 15:38:13
User entered 'TAPER OVER 16 DAYS' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:38:13
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	05 Nov 2020 15:37:45
User entered empty.	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '21 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User entered empty.	System	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User entered empty.	System	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:19:48
User entered empty.	System	05 Nov 2020 15:37:45

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: MINERALS NOS;VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMINS;MINERALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 06:59:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 06:59:52
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: MINERALS NOS;VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:34:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:34:20
Data point term sent to Coder	System	05 Nov 2020 15:39:28
User entered 'MULTI-VITAMIN WITH MINERALS'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User closed query 'Per DM CLR: For medications with multiple components, please review if the number of TABLETS would be a more appropriate dose and unit (e.g. Dose=1 Unit=Tablet). Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:27:47
Query 'Per DM CLR: For medications with multiple components, please review if the number of TABLETS would be a more appropriate dose and unit (e.g. Dose=1 Unit=Tablet). Update as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 15:09:28
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 15:09:15
User opened query 'Per DM CLR: For medications with multiple components, please review if the number of TABLETS would be a more appropriate dose and unit (e.g. Dose=1 Unit=Tablet). Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 00:21:07
User entered '0.5'	douglas winter (b) (4) (b) (4)	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Albert Garcia (b) (4)	28 Dec 2020 15:09:15
User entered 'mg (mg)'	(b) (4)	
	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'once daily (QD)'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Oral (ORAL)'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '5 Oct 2020'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered '0'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered empty.	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	05 Nov 2020 15:39:05
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 15:39:05

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALMETEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Dec 2020 10:36:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:36:24
Data point term sent to Coder	System	01 Dec 2020 14:28:06
User entered 'salmeterol'	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'pulmonary fibrosis'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '50'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'ug (ug)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'twice daily (BID)'	gail lavine (b) (4)	01 Dec 2020 14:27:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'un Apr 2020'	gail lavine (b) (4)	01 Dec 2020 14:27:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
User entered 'Yes (Y)'	gail lavine (b) (4)	01 Dec 2020 14:27:44
	(b) (4)	

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 14:27:44

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN, PRODUCTSYNONYM: O2 [OXYGEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:41:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:41:29
Data point term sent to Coder	System	18 Mar 2021 13:04:58
Coding entries removed.	(b) (4), (b) (6)	18 Mar 2021 13:04:53
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN, PRODUCTSYNONYM: O2 [OXYGEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:13:36
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:07:00
Data point term sent to Coder	System	05 Mar 2021 13:57:26
User entered 'O2 therapy'	(b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:33:39
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	18 Mar 2021 13:05:07
' answered with 'CONNECTED TO AE' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 13:04:53
User entered 'O2 NEEDED DURING PROCEDURE, BRONCHOLAVAGE' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 13:04:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	18 Mar 2021 11:48:08
' (Site from DM).		
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'O2 needed during procedure'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '4'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'LPM'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User entered empty.	System	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User entered empty.	System	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:05:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:23:10
User entered empty.	System	05 Mar 2021 13:57:08

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:05:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:55
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	26 Oct 2020 16:51:43
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Oct 2020 15:48:06

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:52:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '25 Sep 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:53:11

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'CT OF CHEST'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:53:11

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:53:11

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:53:11

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:48
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '24 Oct 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:54:40

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:48
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'XR OF CHEST'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:54:40

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:48
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 11:13:23
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'PLEASE REVIEW AE ENTRY AS THERE IS A RESPIRATORY INDICATION NOTED FOR THIS ASSESSMENT. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:39:17
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:26:04
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:54:40

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:48
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:54:40

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '1 Oct 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:57:52

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'BRONCH LAVAGE RIGHT MIDDLE LOBE OF LUNG'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:57:52

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:57:52

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:57:52

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '2 Oct 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:08

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'BARIUM SWALLOW'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:08

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 11:38:23
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'PLEASE REVIEW AE ;AGE AS THE INDICATION FOR THIS ASSESSMENT IS PRESENT.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:39:48
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:08

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:08

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '27 Sep 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:59

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'XR CHEST'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:59

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:59

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:15:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 16:59:59

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:03
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered '24 Sep 2020'	douglas winter (b) (4) (b) (4)	26 Oct 2020 17:04:21

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:03
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'ELECTRO CARDIO GRAM'	douglas winter (b) (4) (b) (4)	26 Oct 2020 17:04:21

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:03
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	26 Oct 2020 17:04:21

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:03
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:03
User entered empty.	douglas winter (b) (4) (b) (4)	26 Oct 2020 17:04:21

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '25 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:07

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Arterial blood gas'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:07

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:07
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 11:32:10
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	04 Mar 2021 14:04:08
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:23:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 15:35:19
User entered 'Adverse Event (AE)'	gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:07

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:07

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '25 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:47

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Nasal cannula'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:47

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:47

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:25:47

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:19
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '25 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:28:01

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:05:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:19
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'emergency bloodwork'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:28:01

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:05:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:19
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:28:01

US3222068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:05:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:16:19
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 13:28:01

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4), (b) (6)	
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4), (b) (6)	
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4)	
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '08/Oct/2020 17:26'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 15:11:09
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered	System	08 Oct 2020 17:26:18
'USA-US104-2020-MRNA-1273-P301000008'		

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '20/Oct/2020 15:11'	System	20 Oct 2020 15:11:22

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:46:02
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 15:11:22

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '22/Oct/2020 14:46'	System	22 Oct 2020 14:46:23

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 14:46:23

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered	System	08 Oct 2020 17:26:18
'USA-US104-2020-MRNA-1273-P301000008'		

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4)	
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '26/Oct/2020 16:40'	System	26 Oct 2020 16:40:46

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 16:40:46

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '27/Oct/2020 08:25'	System	27 Oct 2020 12:25:42

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 18:11:25
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 12:25:42

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4)	
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4)	
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '05/Nov/2020 18:11'	(b) (4) System	05 Nov 2020 18:11:36

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:42:18
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 18:11:36

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'USA-US104-2020-MRNA-1273-P301000008'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '30/Nov/2020 10:42'	(b) (4) System	30 Nov 2020 15:42:30

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:42:30

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered	System	08 Oct 2020 17:26:18
'USA-US104-2020-MRNA-1273-P301000008'		

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4), (b) (6)	
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '05/Mar/2021 10:27'	(b) (4) System	05 Mar 2021 15:27:08

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:27:08

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered	System	08 Oct 2020 17:26:18
'USA-US104-2020-MRNA-1273-P301000008'		

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Yes (Y)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'No (N)'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Bruce'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Teresa'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Lisa'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Tracy'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Tracy'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Rankin'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered 'Becker'	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Holloway'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered 'Kowalski'	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:26:33
User entered 'Kowalski'	System	08 Oct 2020 17:26:18

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '860 Peachwood Ave'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '6550 Mapleridge Street'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered 'Deland'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'Houston'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:24:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:07:00
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 15:27:08
Signature has been broken.	System	05 Mar 2021 15:27:08
User entered empty.	System	05 Mar 2021 15:27:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
Un-reviewed for Safety.	(b) (4)	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered 'TX'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
	(b) (4)	
Un-reviewed for Safety.	System	16 Mar 2021 15:24:45
Signature has been broken.	System	16 Mar 2021 15:24:45
User entered '32720'	System	16 Mar 2021 15:24:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:26:41
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
Un-reviewed for Safety.	System	30 Nov 2020 15:42:30
DataPoint Un-verified.	System	30 Nov 2020 15:42:30
User entered '77081'	System	30 Nov 2020 15:42:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:58:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:41:11
	(b) (4)	
Un-reviewed for Safety.	System	26 Oct 2020 16:40:46
User entered empty.	System	26 Oct 2020 16:40:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:40:18
	(b) (4)	
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 17:10:48
	(b) (4)	

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:58:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 17:27:25
User entered 'US'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	16 Mar 2021 15:24:45
User entered '8'	System	05 Mar 2021 15:27:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:35:19
	(b) (4)	
User entered '7'	System	30 Nov 2020 15:42:30
User entered '6'	System	05 Nov 2020 18:11:36
User entered '5'	System	27 Oct 2020 12:25:42
User entered '4'	System	26 Oct 2020 16:40:46
User entered '3'	System	22 Oct 2020 14:46:23
User entered '2'	System	20 Oct 2020 15:11:22
User entered '1'	System	08 Oct 2020 17:26:55

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:05:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered '16/Mar/2021 11:24'	(b) (4) System	16 Mar 2021 15:24:45

US3222068

Folder: SAE USA-US104-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:05:47

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.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:04
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:24:45