

US3222524 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:57

All time stamps listed in this document are displayed in GMT

US3222524

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 19:59:44

Generated On: 09 Jun 2021 16:05:57

[Participant ID](#)

US3222524

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

US3222524

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 21:26:28

Generated On: 09 Jun 2021 16:05:57

Date of Birth (MMM yyyy)	(b) (6) 1941
Age	79
Age Units	YEARS
Age (Derived)	79
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Condition	PACEMAKER PLACEMENT
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3222524

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3222524

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Condition	ALLERGIES, SHELLFISH
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

US3222524

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Condition	SEVERE OBESITY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:43 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 10:43
Height (<i>xxx.x</i>)	155.2 cm
Weight (<i>xxx.x</i>)	105.2 kg
BMI (<i>xxx.x</i>)	43.67494 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:55

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:55

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

What was the date of randomization? (dd MMM yyyy) 05 SEP 2020

What was the participant's randomization number? 190128

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☒ No ☐

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 SEP 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 10:52
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 SEP 2020
Time of assessment (00:00-23:59)	12:58 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 12:58
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 5 SEP 2020

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 5 SEP 2020 12:27

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 SEP 2020
Collection time (00:00-23:59)	11:09 (24 HR)
Collection date and time (derived)	5 SEP 2020 11:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)			5 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:11	5 SEP 2020 11:11
Nasopharyngeal Swab 2	No		

US3222524

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:47

PC Close Date & Time

05 SEP 2020 15:17

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	05 SEP 2020 20:21
PC Open Date & Time	05 SEP 2020 16:12
PC Close Date & Time	06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 20:15

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 17:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

10 SEP 2020 19:47

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

11 SEP 2020 18:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:47

PC Close Date & Time

05 SEP 2020 15:17

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:23

PC Open Date & Time

05 SEP 2020 16:12

PC Close Date & Time

06 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:47

PC Close Date & Time

05 SEP 2020 15:17

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 16:12

PC Close Date & Time

06 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

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Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:52
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 SEP 2020 12:25

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

PC Time stamp

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	13 SEP 2020 12:00
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PC Close Date & Time	14 SEP 2020 11:59
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PC Time stamp	13 SEP 2020 12:25
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US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 12:26
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222524

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 11:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:20
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 9 OCT 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 12:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3222524

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	9 OCT 2020 11:55

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:20	9 OCT 2020 12:20
Nasopharyngeal Swab 2	No		

US3222524

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 13:05

PC Close Date & Time

09 OCT 2020 15:35

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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 09 OCT 2020 16:30

PC Close Date & Time 10 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 13:05

PC Close Date & Time

09 OCT 2020 15:35

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

09 OCT 2020 16:30

PC Close Date & Time

10 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

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

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 13:05

PC Close Date & Time

09 OCT 2020 15:35

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 16:30

PC Close Date & Time

10 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

114 of 2698

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

116 of 2698

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

118 of 2698

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

Yes ☐

PC Time stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3222524

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222524

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222524

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:02:48

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 NOV 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

3 NOV 2020 11:00

US3222524

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:55

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 14:53:54

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 10:13:17

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 MAR 2021 10:03:25
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3222524

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 10:50:04

US3222524

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 21:51:02

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3222524

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3222524

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3222524

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3222524

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222524

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:57

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3222524

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:05:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222524

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

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

Visit date (dd MMM yyyy)	17 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3222524

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Date of updated informed consent (<i>dd MMM yyyy</i>)	17 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	17 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3222524

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Height	
Weight	
BMI (xxx.x)	

US3222524

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 JAN 2021
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	17 JAN 2021 08:19
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 JAN 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	17 JAN 2021 09:10
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 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)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 JAN 2021

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

US3222524

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 17 JAN 2021

What was the treatment time? (00:00-23:59) 08:40 (24 HR)

Treatment Date and Time (derived) 17 JAN 2021 08:40

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

US3222524

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

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

Collection date (dd MMM yyyy)	17 JAN 2021
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Collection time (00:00-23:59)	08:05 (24 HR)
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Collection date and time (derived)	17 JAN 2021 08:05
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US3222524

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 JAN 2021
Collection time (00:00 - 23:59)	08:08
Collection Date and Time (derived)	17 JAN 2021 08:08

US3222524

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 FEB 2021
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	14 FEB 2021 11:32
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 FEB 2021
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	14 FEB 2021 12:23
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222524

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 FEB 2021

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

US3222524

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 FEB 2021

What was the treatment time? (00:00-23:59) 11:53 (24 HR)

Treatment Date and Time (derived) 14 FEB 2021 11:53

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

US3222524

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:59:45

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 19:05:11

Generated On: 09 Jun 2021 16:05:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments SPOKE WITH SUBJECT/ NO NEW
MEDICATION/ NO ILLNESS/ NO
COVID SYMPTOMS/ (b) (6)

If Contact Not Made, please provide Comments

US3222524

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 19:05:11

Generated On: 09 Jun 2021 16:05:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222524

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3222524

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3222524

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3222524

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3222524

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 21:26:28

Generated On: 09 Jun 2021 16:05:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

AEID	USA-US104-2021-MRNA-1273-P30 1000012
Adverse event	CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

TODAY AT 1230 PT WIFE
STATED AT HER APPOINTMENT
THAT THE SUBJECT IS
CURRENTLY IN THE HOSPITAL
WENT IN ON 01MAR2021 FOR
SHORTNESS OF BREATH AND IS
STILL CURRENTLY IN DELAND
HOSPITAL. WE WILL SEND A
RECORD RELEASE FOR
RECORDS

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

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

AEID	USA-US104-2021-MRNA-1273-P30 1000012
Adverse event	SUPRA THERAPEUTIC INR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

SUBJECT US3222524 WAS
TAKEN BY AMBULANCE ON
12MAR2021. WIFE STATES
SUBJECT EXPIRED AT THE
HOSPITAL, WE HAVE
REQUESTED RECORDS AND WE
HAVE BEEN PROVIDED A
DEATH CERTIFICATE PRIMARY
CAUSE IS SUPRA THERAPEUTIC
INR SECONDARY
GASTROINTESTINAL BLEED
AND THIRD CAUSE IS
CONGESTIVE HEART FAILURE

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)	

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

AEID	USA-US104-2021-MRNA-1273-P30 1000012
Adverse event	GASTROINTESTINAL BLEED
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

SECONDARY SAE TO SAE # 2
SUBJECT US3222524 WAS
TAKEN BY AMBULANCE ON
12MAR2021. WIFE STATES
SUBJECT EXPIRED AT THE
HOSPITAL, WE HAVE
REQUESTED RECORDS AND WE
HAVE BEEN PROVIDED A
DEATH CERTIFICATE PRIMARY
CAUSE IS SUPRA THERAPEUTIC
INR SECONDARY
GASTROINTESTINAL BLEED
AND THIRD CAUSE IS
CONGESTIVE HEART FAILURE

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

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

AEID	USA-US104-2021-MRNA-1273-P30 1000012
Adverse event	CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

SECONDARY SAE. SEE
PRIMARY SAE #2 SUBJECT
US3222524 WAS TAKEN BY
AMBULANCE ON 12MAR2021.
WIFE STATES SUBJECT
EXPIRED AT THE HOSPITAL,
WE HAVE REQUESTED
RECORDS AND WE HAVE BEEN
PROVIDED A DEATH
CERTIFICATE PRIMARY CAUSE
IS SUPRA THERAPEUTIC INR
SECONDARY
GASTROINTESTINAL BLEED
AND THIRD CAUSE IS
CONGESTIVE HEART FAILURE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 19:59:44

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:02:46

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:02:46

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:02:46

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Name of Medication ACETAMINOPHEN ER

Prophylaxis Yes ☐
No ☒

Indication BACK 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication AMLODIPINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:02:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication CALCIUM CITRATE W/VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:02:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication COLACE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication BLOOD THINNER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication LOW CORTICOSTEROID LEVEL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 65

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication LACTULOSE

Prophylaxis Yes ☒
No ☐

Indication INTERMITTENT CONSTIPATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication NITROGLYCERINE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication SUPER B/C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERTROPHY

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication VITAMIN D-3

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 325/10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication BLOOD THINNER

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication DONEPEZIL

Prophylaxis Yes ☐
No ☒

Indication DEMENTIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication ROPINEROLE

Prophylaxis Yes ☐
No ☒

Indication TREMORS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication SILDENAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication WARFARIN

Prophylaxis Yes ☐
No ☒

Indication A-FIB

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

Name of Medication ALENDRONATE

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:02:46

Generated On: 09 Jun 2021 16:05:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 MAR 2021	CHEST XR	Adverse Event	
02 MAR 2021	ECHOCARDIOGRAM	Adverse Event	

US3222524

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:57

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

Date of study discontinuation/completion (dd MMM yyyy) 12 MAR 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input checked="" type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 12 MAR 2021

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/MAR/2021 17:05
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

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/MAR/2021 08:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/MAR/2021 09:58
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

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/MAR/2021 08:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/MAR/2021 08:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/APR/2021 12:45
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

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/APR/2021 06:17
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

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 15:02:47

Generated On: 09 Jun 2021 16:05:57

SAEID	USA-US104-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/APR/2021 10:59
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

US3222524 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222524

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:57

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'US3222524'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:41

US3222524

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:47

US3222524

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '05 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:43

US3222524

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:47

US3222524

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'SCRN'	System	05 Sep 2020 16:36:47

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1941) recorded on this form but not reported in PPD Central lab. Please review the source and confirm. Else clarify, thank you' (Site from DM). User signature succeeded.	(b) (4)	10 Mar 2021 13:08:58
	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1941) recorded on this form but not reported in PPD Central lab. Please review the source and confirm. Else clarify, thank you' answered with 'DOB is (b) (6) 1941' (Site from DM).	Jennifer Dittman (b) (4)	05 Mar 2021 17:38:49
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1941) recorded on this form but not reported in PPD Central lab. Please review the source and confirm. Else clarify, thank you' (Site from DM). User entered (b) (6) 1941'	(b) (4), (b) (6)	05 Feb 2021 09:48:18
	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:44

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '79'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'YEARS'	System	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '79'	System	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL Lab Recon: Sex (Male) recorded on this form, however its not reported in PPD central lab. Please reconcile the data and confirm. Else clarify, thank you' (Site from DM).		10 Mar 2021 13:09:04
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL Lab Recon: Sex (Male) recorded on this form, however its not reported in PPD central lab. Please reconcile the data and confirm. Else clarify, thank you' answered with 'Male' (Site from DM).	(b) (4) Jennifer Dittman (b) (4)	05 Mar 2021 17:39:15
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL Lab Recon: Sex (Male) recorded on this form, however its not reported in PPD central lab. Please reconcile the data and confirm. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:48:53
User entered 'Male (M)'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'I'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:10:24

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '5 Sep 2020'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Sep 2020'	System	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '2020'	System	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Amendment 3 (3)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:36:58

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:43

US3222524

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'I'	System	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:57

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:12:21

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:17:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:17:42
Data point term sent to Coder	System	05 Sep 2020 18:16:41
User entered 'Pacemaker Placement'	Albert Garcia (b) (4)	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'un UNK 2013'	Albert Garcia (b) (4)	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 06:59:19
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'CORRECTION COMPLETETD' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	26 Oct 2020 19:45:52
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	26 Oct 2020 19:45:31
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:24:51
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'UN UNK 2013' reason for change:	(b) (4)	
Data Entry Error	Alicia Cevera (b) (4)	26 Oct 2020 19:45:31
User entered empty.	(b) (4)	
	Albert Garcia (b) (4)	05 Sep 2020 18:16:00
	(b) (4)	

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Jan 2013'	System	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '2013'	System	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Jan 2013'	System	26 Oct 2020 19:45:31
User entered empty.	System	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '2013'	System	26 Oct 2020 19:45:31
User entered empty.	System	05 Sep 2020 18:16:00

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:18:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:18:42
Data point term sent to Coder	System	05 Sep 2020 18:17:42
User entered 'Atrial fibrillation'	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'un UNK 2013'	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Jan 2013'	System	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '2013'	System	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:17:19

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 04:18:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 04:18:41
Data point term sent to Coder	System	05 Sep 2020 18:18:42
User entered 'Allergies, Shellfish'	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'un UNK 1960'	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Jan 1960'	System	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '1960'	System	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:18:21

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 18:20:42
Data point term sent to Coder	System	05 Sep 2020 18:19:42
User entered 'Severe Obesity'	Albert Garcia (b) (4)	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'un UNK 2012'	Albert Garcia (b) (4)	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
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	05 Sep 2020 18:19:14
User entered 'Yes (Y)' reason for change: Data Entry Error	System	05 Sep 2020 18:19:14
User opened query 'Data is required. Please complete.' (Site from System).	Albert Garcia (b) (4)	05 Sep 2020 18:19:14
User entered empty.	(b) (4)	
	System	05 Sep 2020 18:19:00
	Albert Garcia (b) (4)	05 Sep 2020 18:19:00
	(b) (4)	

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'Jan 2012'	System	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '2012'	System	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	05 Sep 2020 18:19:00

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:31:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:31:57
Data point term sent to Coder	System	30 Oct 2020 19:31:22
User entered 'gastroesophageal reflux disease'	Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:31:06

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:32:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:32:55
Data point term sent to Coder	System	30 Oct 2020 19:32:25
User entered 'degenerative disk disease'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:15

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
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)	30 Oct 2020 19:33:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:33:56
Data point term sent to Coder	System	30 Oct 2020 19:33:28
User entered 'hypercholesterolemia'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:32:46

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User closed query 'Per MM, please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:10
Query 'Per MM, please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' answered with 'STABLE' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Nov 2020 14:15:23
User opened query 'Per MM, please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:00:23
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)	30 Oct 2020 19:33:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:33:55
Data point term sent to Coder	System	30 Oct 2020 19:33:29
User entered 'hypertension'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:02

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:33:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:33:55
Data point term sent to Coder	System	30 Oct 2020 19:33:28
User entered 'depression'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:33:18

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:35:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 19:35:57
Data point term sent to Coder	System	30 Oct 2020 19:35:29
User entered 'coronary artery disease'	Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '0'	Alicia Cevera (b) (4)	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	30 Oct 2020 19:35:08

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:32:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:32:23
Data point term sent to Coder	System	06 Apr 2021 20:31:39
User entered 'BENIGN PROSTATIC HYPERTROPHY'	(b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:30:48

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:32:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:32:23
Data point term sent to Coder	System	06 Apr 2021 20:31:39
User entered 'neuropathy'	(b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	06 Apr 2021 20:31:19

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 12:09:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 12:09:47
Data point term sent to Coder	System	22 Apr 2021 12:09:27
User entered 'OSTEOPOROSIS'	douglas winter (b) (4)	22 Apr 2021 12:08:53
	(b) (4)	

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	douglas winter (b) (4)	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered empty.	System	22 Apr 2021 12:08:53

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '10:43'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '5 Sep 2020 10:43'	System	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '155.2' cm	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:22:29
DataPoint set to visible.	(b) (4) System	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '105.2' kg	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
DataPoint set to visible.	System	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered '43.67494'	System	05 Sep 2020 18:22:29
DataPoint set to visible.	System	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'kg/m2'	System	05 Sep 2020 18:22:29
DataPoint set to visible.	System	05 Sep 2020 16:37:02

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:34:12
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 16:25:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 16:25:30
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:16:56
User entered '36.8' C	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	06 Oct 2020 16:25:30
User entered 'Oral (Oral)'	(b) (4)	
	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
	(b) (4)	

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:25:30
User entered '61'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
	(b) (4)	

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'bpm'	System	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:25:30
User entered '17'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
	(b) (4)	

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'breaths/min'	System	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:25:30
User entered '139'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
	(b) (4)	

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'mmHg'	System	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:25:30
User entered '80'	Albert Garcia (b) (4)	05 Sep 2020 18:22:29
	(b) (4)	

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User entered 'mmHg'	System	05 Sep 2020 18:22:29

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13

US3222524

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13

US3222524

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:22:37

US3222524

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	Albert Garcia (b) (4)	05 Sep 2020 18:22:37

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

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)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[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)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

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)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

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)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

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)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'I'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '0'	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:32:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:23:10

US3222524

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:23:28

US3222524

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	Albert Garcia (b) (4)	05 Sep 2020 18:23:28

US3222524

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	05 Sep 2020 18:23:28

US3222524

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'VISIT1'	System	05 Sep 2020 18:23:28

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '05 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:48

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '190128'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:48

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 16:10:48

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Sep 2020 18:26:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 18:26:28
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Sep 2020 18:26:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Sep 2020 18:26:17
User entered empty.	System	05 Sep 2020 18:26:17
	Albert Garcia (b) (4)	05 Sep 2020 18:26:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:26:17

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:26:17

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:26:17

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:26:17

US3222524

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:57

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	05 Oct 2020 12:19:16
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:32:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:32:46

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
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)	13 Oct 2020 13:34:01
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 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:31
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 19:45:42
User entered empty.	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 12:19:31
User entered empty.	Alicia Cevera (b) (4)	05 Sep 2020 18:30:16
	(b) (4)	

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
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)	13 Oct 2020 13:34:01
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 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:31
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 19:45:42
User entered empty.	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 12:19:31
User entered empty.	Alicia Cevera (b) (4)	05 Sep 2020 18:30:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:30:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '10:52'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered '5 Sep 2020 10:52'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '36.8' C	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '61'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'bpm'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '14'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'breaths/min'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '144'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'mmHg'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '83'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'mmHg'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
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)	13 Oct 2020 13:34:01
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 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	05 Oct 2020 12:19:31
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 19:45:42
User entered empty.	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 12:19:31
User entered empty.	Alicia Cevera (b) (4)	05 Sep 2020 18:30:16
	(b) (4)	

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '12:58'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered '5 Sep 2020 12:58'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '36.8' C	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '60'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'bpm'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '15'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'breaths/min'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:45:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:32
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 18:30:16
User entered '168'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'mmHg'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '89'	Albert Garcia (b) (4)	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'mmHg'	System	05 Sep 2020 18:30:16

US3222524

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:30:44

US3222524

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:30:44

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '5 Sep 2020'	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '12:27'	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered '5 Sep 2020 12:27'	System	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'ONCE'	System	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 16:37:38

US3222524

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:31:01

US3222524

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' answered with 'Change Request Form sent into PPD to correct this.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 05:04:25
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' answered with 'Change Request Form sent into PPD to correct this.' (Site from DM).	Bruce Rankin (b) (4) (b) (4)	19 Apr 2021 19:44:24
User entered '5 Sep 2020'	(b) (4), (b) (6)	17 Nov 2020 07:17:44
	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:31:01

US3222524

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '11:09'	Albert Garcia (b) (4)	05 Sep 2020 18:31:01

US3222524

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered '5 Sep 2020 11:09'	System	05 Sep 2020 18:31:01

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 07:35:52
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Change Request Form was sent to PPD to correct this. ' (Site from DM).	Bruce Rankin (b) (4) (b) (4)	19 Apr 2021 19:44:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:22:46
User entered '5 Sep 2020'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '11:11'	Albert Garcia (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered '5 Sep 2020 11:11'	System	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Albert Garcia (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Albert Garcia (b) (4)	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered empty.	System	05 Sep 2020 18:31:15

US3222524

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	05 Sep 2020 18:31:21

US3222524

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:38
User entered 'I'	System	05 Sep 2020 18:31:21

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 12:47'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 15:17'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:19:33', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7378e12d-9879-46db-b831-2e382462049d' User entered 'Yes (Y)'	System	06 Sep 2020 00:21:08
	System	06 Sep 2020 00:21:08

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:20:28', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7378e12d-9879-46db-b831-2e382462049d' User entered '97.6'	System	06 Sep 2020 00:21:08
	System	06 Sep 2020 00:21:08

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:20:43', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7378e12d-9879-46db-b831-2e382462049d' User entered 'No (N)'	System	06 Sep 2020 00:21:08
	System	06 Sep 2020 00:21:08

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:21:02', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7378e12d-9879-46db-b831-2e382462049d' User entered '05 Sep 2020 20:21'	System	06 Sep 2020 00:21:08
	System	06 Sep 2020 00:21:08

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 16:12'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 2'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:15:26', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e' User entered 'Yes (Y)'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:13:58', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e' User entered '97.3'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:14:10', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e' User entered 'Yes (Y)'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT MADE THIS ENTRY IN ERROR. ' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 08:50:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	03 Nov 2020 17:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:14:46', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e'	(b) (4)	
User entered '1'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:14:46', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e' User entered '0'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-06T20:15:31', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '3fb1423e-4d97-483d-951b-14ccf266e40e' User entered '06 Sep 2020 20:15'	System	08 Sep 2020 21:27:56
	System	08 Sep 2020 21:27:56

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 3'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 4'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-08T17:28:47', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7dd022c0-b1c4-480b-a530-318cfa8314b6' User entered 'Yes (Y)'	System	08 Sep 2020 21:29:24
	System	08 Sep 2020 21:29:24

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-08T17:29:07', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7dd022c0-b1c4-480b-a530-318cfa8314b6' User entered '97.4'	System	08 Sep 2020 21:29:24
	System	08 Sep 2020 21:29:24

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-08T17:29:14', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7dd022c0-b1c4-480b-a530-318cfa8314b6' User entered 'No (N)'	System	08 Sep 2020 21:29:24
	System	08 Sep 2020 21:29:24

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-08T17:29:20', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '7dd022c0-b1c4-480b-a530-318cfa8314b6' User entered '08 Sep 2020 17:29'	System	08 Sep 2020 21:29:24
	System	08 Sep 2020 21:29:24

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 5'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 6'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-10T19:46:59', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'c6426372-28fb-4c38-800c-1ec41bea368a' User entered 'Yes (Y)'	System	10 Sep 2020 23:47:42
	System	10 Sep 2020 23:47:42

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-10T19:46:36', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'c6426372-28fb-4c38-800c-1ec41bea368a' User entered '97.0'	System	10 Sep 2020 23:47:42
	System	10 Sep 2020 23:47:42

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-10T19:46:46', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'c6426372-28fb-4c38-800c-1ec41bea368a' User entered 'No (N)'	System	10 Sep 2020 23:47:42
	System	10 Sep 2020 23:47:42

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-10T19:47:40', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'c6426372-28fb-4c38-800c-1ec41bea368a' User entered '10 Sep 2020 19:47'	System	10 Sep 2020 23:47:42
	System	10 Sep 2020 23:47:42

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 7'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:39:50', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '279db07b-bea4-4715-adb3-68c9fcb18264' User entered 'Yes (Y)'	System	11 Sep 2020 22:40:32
	System	11 Sep 2020 22:40:32

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:39:12', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '279db07b-bea4-4715-adb3-68c9fcb18264' User entered '97.2'	System	11 Sep 2020 22:40:32
	System	11 Sep 2020 22:40:32

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:39:26', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '279db07b-bea4-4715-adb3-68c9fcb18264' User entered 'No (N)'	System	11 Sep 2020 22:40:32
	System	11 Sep 2020 22:40:32

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:40:16', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '279db07b-bea4-4715-adb3-68c9fcb18264' User entered '11 Sep 2020 18:40'	System	11 Sep 2020 22:40:32
	System	11 Sep 2020 22:40:32

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 12:47'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 15:17'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:22:25', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'af78e319-b8f8-4e1a-bf62-ca104306aa2d' User entered 'None (1)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:22:41', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'af78e319-b8f8-4e1a-bf62-ca104306aa2d' User entered 'No (N)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:22:55', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'af78e319-b8f8-4e1a-bf62-ca104306aa2d' User entered 'No (N)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:23:20', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'af78e319-b8f8-4e1a-bf62-ca104306aa2d' User entered 'None (1)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-05T20:23:33', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'af78e319-b8f8-4e1a-bf62-ca104306aa2d' User entered '05 Sep 2020 20:23'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 16:12'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 2'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 3'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 4'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 5'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 6'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 7'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 12:47'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 15:17'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '05 Sep 2020 16:12'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 2'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 3'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 4'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 5'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 6'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 7'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:52:13', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0' User entered 'None (0)'	System	11 Sep 2020 22:52:25
	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:44:17', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0'	System	11 Sep 2020 22:52:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:45:34', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0' User entered 'None (0)'	System	11 Sep 2020 22:52:25
	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:48:50', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0'	System	11 Sep 2020 22:52:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:48:44', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0' User entered 'None (0)'	System	11 Sep 2020 22:52:25
	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:49:25', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0'	System	11 Sep 2020 22:52:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:50:31', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0'	System	11 Sep 2020 22:52:25
User entered 'No (N)'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-11T18:52:21', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '23a9f3c9-0cdf-4df4-b20e-407ee32fe6a0'	System	11 Sep 2020 22:52:25
User entered '11 Sep 2020 18:52'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 8'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 9'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:24:25', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '0c20253c-2a7e-48bb-bffa-7a1ab8221ca2' User entered 'None (0)'	System	13 Sep 2020 16:25:15
	System	13 Sep 2020 16:25:15

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:25:09', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '0c20253c-2a7e-48bb-bffa-7a1ab8221ca2'	System	13 Sep 2020 16:25:15
User entered '13 Sep 2020 12:25'	System	13 Sep 2020 16:25:15

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 8'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 9'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:25:18', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '2b54f136-c8cd-4190-88bc-c5304aa35bdd' User entered 'None (0)'	System	13 Sep 2020 16:25:39
	System	13 Sep 2020 16:25:39

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:25:36', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '2b54f136-c8cd-4190-88bc-c5304aa35bdd' User entered '13 Sep 2020 12:25'	System	13 Sep 2020 16:25:39
	System	13 Sep 2020 16:25:39

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 8'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 9'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:25:42', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'ceb08da8-8253-4205-8fb5-d7304d754ad4' User entered 'None (0)'	System	13 Sep 2020 16:25:55
	System	13 Sep 2020 16:25:55

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:25:50', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: 'ceb08da8-8253-4205-8fb5-d7304d754ad4' User entered '13 Sep 2020 12:25'	System	13 Sep 2020 16:25:55
	System	13 Sep 2020 16:25:55

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 8'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	11 Sep 2020 22:52:25
User entered 'Day 9'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:26:05', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '9ae1c372-f602-4444-9d02-d03d0426ebef' User entered 'No (N)'	System	13 Sep 2020 16:26:17
	System	13 Sep 2020 16:26:17

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-09-13T12:26:16', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '9ae1c372-f602-4444-9d02-d03d0426ebef' User entered '13 Sep 2020 12:26'	System	13 Sep 2020 16:26:17
	System	13 Sep 2020 16:26:17

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:52:25

US3222524

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:52:25

US3222524

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:49:08

US3222524

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '12 Sep 2020'	Jennifer Dittman (b) (4)	03 Oct 2020 14:49:08

US3222524

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:49:08

US3222524

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Jennifer Dittman (b) (4)	03 Oct 2020 14:49:08

US3222524

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:49:13

US3222524

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered 'I'	System	03 Oct 2020 14:49:13

US3222524

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:52:51

US3222524

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '19 Sep 2020'	Jennifer Dittman (b) (4)	03 Oct 2020 14:52:51

US3222524

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:52:51

US3222524

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Jennifer Dittman (b) (4)	03 Oct 2020 14:52:51

US3222524

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:52:57

US3222524

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User entered 'I'	System	03 Oct 2020 14:52:57

US3222524

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:54:40

US3222524

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '26 Sep 2020'	Jennifer Dittman (b) (4)	03 Oct 2020 14:54:40

US3222524

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:54:40

US3222524

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Jennifer Dittman (b) (4)	03 Oct 2020 14:54:40

US3222524

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Oct 2020 14:54:48

US3222524

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:30:59
User entered 'I'	System	03 Oct 2020 14:54:48

US3222524

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:23

US3222524

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:23

US3222524

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:23

US3222524

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'VISIT2'	System	09 Oct 2020 16:55:23

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
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	12 Oct 2020 12:36:22
User entered 'Yes (Y)' reason for change: Data Entry Error	System	12 Oct 2020 12:36:22
User opened query 'Data is required. Please complete.' (Site from System).	Albert Garcia (b) (4)	12 Oct 2020 12:36:22
User entered empty.	(b) (4)	
	System	12 Oct 2020 12:36:17
	Albert Garcia (b) (4)	12 Oct 2020 12:36:17
	(b) (4)	

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Oct 2020 12:36:32
User entered '9 Oct 2020' reason for change: Data Entry Error	System	12 Oct 2020 12:36:32
User opened query 'Data is required. Please provide.' (Site from System).	Albert Garcia (b) (4)	12 Oct 2020 12:36:22
User entered empty.	(b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '11:25'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '9 Oct 2020 11:25'	System	12 Oct 2020 12:36:32
User entered empty.	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '36.7' C	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '60'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'bpm'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '14'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'breaths/min'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '127'	(b) (4) Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'mmHg'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '88'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'mmHg'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '9 Oct 2020'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Oct 2020 14:49:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Oct 2020 14:49:31
User entered '13:20' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	14 Oct 2020 14:49:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Oct 2020 12:36:17
User entered empty.	Albert Garcia (b) (4)	12 Oct 2020 12:36:17
	(b) (4)	

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '9 Oct 2020 13:20'	System	14 Oct 2020 14:49:31
User entered empty.	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '36.5' C	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '61'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'bpm'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	14 Oct 2020 14:49:31
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).		14 Oct 2020 14:49:31
User entered '15' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	14 Oct 2020 14:49:31
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	12 Oct 2020 12:36:17
User entered '140'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'breaths/min'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Oct 2020 14:49:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Oct 2020 14:49:31
User entered '140' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	14 Oct 2020 14:49:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Oct 2020 12:36:17
User entered empty.	Albert Garcia (b) (4)	12 Oct 2020 12:36:17
	(b) (4)	

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'mmHg'	System	14 Oct 2020 14:49:31
User entered empty.	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '90'	Albert Garcia (b) (4)	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'mmHg'	System	12 Oct 2020 12:36:17

US3222524

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	12 Oct 2020 12:32:24

US3222524

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '9 Oct 2020'	Albert Garcia (b) (4)	12 Oct 2020 12:32:24

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '12:45'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '9 Oct 2020 12:45'	System	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'ONCE'	System	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 16:55:50

US3222524

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	12 Oct 2020 12:31:46

US3222524

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' answered with 'A CHANGE REQUEST FORM HAS BEEN SUBMITTED TO PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 05:05:16
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM).	Bruce Rankin (b) (4) (b) (4)	19 Apr 2021 20:09:08
User entered '9 Oct 2020'	(b) (4), (b) (6)	04 Dec 2020 14:14:06
	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:31:46

US3222524

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '11:55' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	12 Oct 2020 12:32:13
User entered '12:20'	(b) (4)	
	Albert Garcia (b) (4)	12 Oct 2020 12:31:46
	(b) (4)	

US3222524

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '9 Oct 2020 11:55'	System	12 Oct 2020 12:32:13
User entered '9 Oct 2020 12:20'	System	12 Oct 2020 12:31:46

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 07:36:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'A CHANGE REQUEST FORM HAS BEEN SUBMITTED TO PPD' (Site from DM).	Bruce Rankin (b) (4) (b) (4)	19 Apr 2021 20:09:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:27:26
User entered '9 Oct 2020'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12:20'	Albert Garcia (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '9 Oct 2020 12:20'	System	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Albert Garcia (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Albert Garcia (b) (4)	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	12 Oct 2020 12:31:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:55:58

US3222524

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'I'	System	09 Oct 2020 16:55:58

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 13:05'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 16:30'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 2'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 3'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 4'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 5'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 6'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 7'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 13:05'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 16:30'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 2'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 3'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 4'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 5'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 6'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 7'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 13:05'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '09 Oct 2020 16:30'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 2'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 3'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 4'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 5'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 6'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
Data entry locked.	System	09 Oct 2020 16:55:50
User entered 'Day 7'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:55:50

US3222524

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:34:13
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:55:50

US3222524

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 13:26:05

US3222524

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '16 Oct 2020'	Alicia Cevera (b) (4)	22 Oct 2020 13:26:05

US3222524

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 13:26:05

US3222524

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 13:26:05

US3222524

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 13:25:56

US3222524

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'I'	System	22 Oct 2020 13:25:56

US3222524

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 19:46:24

US3222524

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '24 Oct 2020'	Alicia Cevera (b) (4)	26 Oct 2020 19:46:24

US3222524

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 19:46:24

US3222524

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	26 Oct 2020 19:46:24

US3222524

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 19:46:29

US3222524

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'I'	System	26 Oct 2020 19:46:29

US3222524

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:29:53

US3222524

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '30 Oct 2020'	Alicia Cevera (b) (4)	30 Oct 2020 19:29:53

US3222524

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:29:53

US3222524

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:29:53

US3222524

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:29:41

US3222524

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'I'	System	30 Oct 2020 19:29:41

US3222524

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	03 Nov 2020 17:45:43

US3222524

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered '3 Nov 2020'	Albert Garcia (b) (4)	03 Nov 2020 17:45:43

US3222524

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	03 Nov 2020 17:45:43

US3222524

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'VISIT3'	System	03 Nov 2020 17:45:43

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered empty.	System	03 Nov 2020 17:45:50

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26

US3222524

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26

US3222524

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'No (N)'	Albert Garcia (b) (4)	03 Nov 2020 17:45:55

US3222524

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered empty.	Albert Garcia (b) (4)	03 Nov 2020 17:45:55

US3222524

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	03 Nov 2020 17:46:07

US3222524

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Samples will be shipped out by EOB today. ' (Site from DM).	(b) (4) (b) (4), (b) (6) Jennifer Dittman (b) (4)	09 Apr 2021 16:27:32 08 Apr 2021 15:24:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '3 Nov 2020'	(b) (4), (b) (6) Albert Garcia (b) (4)	04 Dec 2020 14:42:33 03 Nov 2020 17:46:07

US3222524

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '11:00'	Albert Garcia (b) (4)	03 Nov 2020 17:46:07

US3222524

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '3 Nov 2020 11:00'	System	03 Nov 2020 17:46:07

US3222524

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	03 Nov 2020 17:46:11

US3222524

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered '1'	System	03 Nov 2020 17:46:11

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 64'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '05 Nov 2020 00:01'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '09 Nov 2020 23:59'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 71'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-11-12T14:53:03', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '857a4053-389a-4ba4-a685-948023db804c' User entered 'No (N)'	System	16 Nov 2020 19:16:47
	System	16 Nov 2020 19:16:47

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-11-12T14:53:16', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '857a4053-389a-4ba4-a685-948023db804c' User entered 'No (N)'	System	16 Nov 2020 19:16:47
	System	16 Nov 2020 19:16:47

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B8051204-A684-45F5-9287-2E055C1142FA)', Time: '2020-11-12T14:53:54', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '857a4053-389a-4ba4-a685-948023db804c' User entered '12 Nov 2020 14:53:54'	System	16 Nov 2020 19:16:47
	System	16 Nov 2020 19:16:47

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '12 Nov 2020 00:01'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:11:03
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '16 Nov 2020 23:59'	System	05 Sep 2020 16:37:38

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered 'Day 78'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

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[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)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

US3222524

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '19 Nov 2020 00:01'	System	05 Sep 2020 16:37:38

US3222524

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 20:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:45:19
Data entry locked.	System	05 Sep 2020 16:37:38
User entered '23 Nov 2020 23:59'	System	05 Sep 2020 16:37:38

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-02-12T10:12:54', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '6a63e3ab-1e52-41c1-8b3e-7b1032045186'	System	12 Feb 2021 15:13:25
User entered 'No (N)'	System	12 Feb 2021 15:13:25

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-02-12T10:13:05', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '6a63e3ab-1e52-41c1-8b3e-7b1032045186'	System	12 Feb 2021 15:13:25
User entered 'No (N)'	System	12 Feb 2021 15:13:25

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-02-12T10:13:17', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '6a63e3ab-1e52-41c1-8b3e-7b1032045186' User entered '12 Feb 2021 10:13:17'	System	12 Feb 2021 15:13:25
	System	12 Feb 2021 15:13:25

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:02:13', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered 'Yes (Y)'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:02:22', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered 'No (N)'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:02:33', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered 'No (N)'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:02:52', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered 'Yes (Y)'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:03:14', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-03-04T10:03:25', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '4915c684-2cc7-4f8c-8683-382c0329509e'	System	04 Mar 2021 15:03:38
User entered '04 Mar 2021 10:03:25'	System	04 Mar 2021 15:03:38

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 05:45:19

US3222524

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:45:19
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 05:45:19

US3222524

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-02-28T10:49:32', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '35c6f736-c382-4076-b5ae-81c6bd0c360d'	System	28 Feb 2021 15:50:08
User entered 'No (N)'	System	28 Feb 2021 15:50:08

US3222524

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7c830f72c621b544)', Time: '2021-02-28T10:50:04', User OID: 'PatientReportedOutcome (US3222524)', ODM File OID: '35c6f736-c382-4076-b5ae-81c6bd0c360d' User entered '28 Feb 2021 10:50:04'	System	28 Feb 2021 15:50:08
	System	28 Feb 2021 15:50:08

US3222524

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	heather jackson (b) (4)	11 Dec 2020 21:00:05

US3222524

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '01 Dec 2020'	heather jackson (b) (4)	11 Dec 2020 21:00:05

US3222524

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	11 Dec 2020 21:00:05

US3222524

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	heather jackson (b) (4)	11 Dec 2020 21:00:05

US3222524

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	heather jackson (b) (4)	11 Dec 2020 21:00:09

US3222524

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:26
User entered 'I'	System	11 Dec 2020 21:00:09

US3222524

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	heather jackson (b) (4)	04 Jan 2021 21:15:07

US3222524

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '04 Jan 2021'	heather jackson (b) (4)	04 Jan 2021 21:15:07

US3222524

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	04 Jan 2021 21:15:07

US3222524

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) heather jackson (b) (4)	04 Jan 2021 21:15:07

US3222524

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	heather jackson (b) (4)	04 Jan 2021 21:15:13

US3222524

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User entered 'I'	System	04 Jan 2021 21:15:13

US3222524

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Apr 2021 00:49:41

US3222524

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	01 Apr 2021 00:49:41

US3222524

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Apr 2021 00:49:41

US3222524

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Apr 2021 00:49:41

US3222524

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:45:14

US3222524

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User entered 'I'	System	01 Mar 2021 18:45:14

US3222524

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:45:34

US3222524

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 10:13:03
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'ADDED TO PD LOG OOW' (Site from System).	douglas winter (b) (4) (b) (4)	14 Apr 2021 18:49:35
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Mar 2021 18:45:34
User entered '01 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 18:45:34

US3222524

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:45:34

US3222524

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:45:34

US3222524

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Apr 2021 00:41:52

US3222524

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:44
User entered 'I'	System	01 Apr 2021 00:41:52

US3222524

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:30:39

US3222524

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:30:39

US3222524

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:30:39

US3222524

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 14:30:39

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:29:32

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:29:32

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '1'	System	20 Jan 2021 14:31:09

US3222524

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'I'	System	20 Jan 2021 14:31:09

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '155.2' cm	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '105.2' kg	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered empty.	System	03 Feb 2021 16:34:00
User entered '43.67494'	System	20 Jan 2021 14:34:15
DataPoint set to visible.	System	20 Jan 2021 14:31:09

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '155.2' cm	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '105.2' kg	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered empty.	System	03 Feb 2021 16:34:00
User entered '43.67494'	System	20 Jan 2021 14:34:15
DataPoint set to visible.	System	20 Jan 2021 14:31:09

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '08:19'	Diana Toney (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '17 Jan 2021 08:19'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '36.9' C	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '70'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'bpm'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '18'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'breaths/min'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '120'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'mmHg'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '69'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'mmHg'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '155.2' cm	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty; reason for change Data Entry Error	(b) (4) gail lavine (b) (4)	03 Feb 2021 16:34:00
User entered '105.2' kg	(b) (4) Diana Toney (b) (4)	20 Jan 2021 14:34:15
	(b) (4)	

US3222524

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered empty.	System	03 Feb 2021 16:34:00
User entered '43.67494'	System	20 Jan 2021 14:34:15
DataPoint set to visible.	System	20 Jan 2021 14:31:09

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '09:10'	Diana Toney (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '17 Jan 2021 09:10'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '36.5' C	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '67'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'bpm'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '18'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'breaths/min'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '118'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'mmHg'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '66'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:15

US3222524

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'mmHg'	System	20 Jan 2021 14:34:15

US3222524

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:32

US3222524

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	Diana Toney (b) (4)	20 Jan 2021 14:34:32

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'mRNA-1273'	System	20 Jan 2021 14:34:58
DataPoint set to visible.	System	20 Jan 2021 14:31:09

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '08:40'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '17 Jan 2021 08:40'	System	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'ONCE'	System	20 Jan 2021 14:34:58

US3222524

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

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 14:34:58

US3222524

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:35:48

US3222524

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:35:48

US3222524

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '08:05'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:35:48

US3222524

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '17 Jan 2021 08:05'	System	20 Jan 2021 14:35:48

US3222524

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:36:11

US3222524

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:57

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '17 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:36:11

US3222524

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '08:08'	Diana Toney (b) (4)	20 Jan 2021 14:36:11

US3222524

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:57

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '17 Jan 2021 08:08'	System	20 Jan 2021 14:36:11

US3222524

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

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 14:36:17

US3222524

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

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:49:46
User entered '1'	System	20 Jan 2021 14:36:17

US3222524

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:55:49

US3222524

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:55:49

US3222524

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:55:49

US3222524

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:55:49

US3222524

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:55:52

US3222524

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User entered 'I'	System	01 Feb 2021 18:55:52

US3222524

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User entered 'I'	System	01 Feb 2021 18:55:52
DataPoint set to visible.	System	01 Feb 2021 18:55:52

US3222524

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:56:08

US3222524

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:56:08

US3222524

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:56:08

US3222524

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'OLD29'	System	15 Feb 2021 10:56:08

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User accepted default value 'Pre-Dose (PREDOSE)'		15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '11:32'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered '14 Feb 2021 11:32'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '60'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'bpm'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'breaths/min'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '123'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'mmHg'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '79'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'mmHg'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '12:23'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered '14 Feb 2021 12:23'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '61'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'bpm'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'breaths/min'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '136'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'mmHg'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '80'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'mmHg'	System	15 Feb 2021 10:57:52

US3222524

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:00

US3222524

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:00

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'mRNA-1273'	System	15 Feb 2021 10:58:15
DataPoint set to visible.	System	01 Feb 2021 18:55:52

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered '11:53'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered '14 Feb 2021 11:53'	System	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'ONCE'	System	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 10:58:15

US3222524

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:58:21

US3222524

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:44
User entered 'I'	System	15 Feb 2021 10:58:21

US3222524

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User signature succeeded.	Bruce Rankin (b) (4)	24 Feb 2021 19:05:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:08:20

US3222524

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User signature succeeded.	Bruce Rankin (b) (4)	24 Feb 2021 19:05:11
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:08:20

US3222524

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User signature succeeded.	Bruce Rankin (b) (4)	24 Feb 2021 19:05:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:08:20

US3222524

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User signature succeeded.	Bruce Rankin (b) (4)	24 Feb 2021 19:05:11
User entered 'spoke with subject/ no new medication/ no illness/ no covid symptoms/ (b) (6)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:08:20

US3222524

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User signature succeeded.	Bruce Rankin (b) (4)	24 Feb 2021 19:05:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:08:25

US3222524

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:00:02
User entered 'I'	System	24 Feb 2021 16:08:25

US3222524

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		21 Apr 2021 15:39:36
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Signature has been broken.	(b) (4)	
	Diana Toney (b) (4)	03 Mar 2021 19:50:18
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Toney (b) (4)	03 Mar 2021 19:50:18
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	09 Oct 2020 16:56:53
	(b) (4)	

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
Reviewed for Safety.		08 Mar 2021 13:06:55
Un-reviewed for Safety.		08 Mar 2021 13:06:51
Reviewed for Safety.		04 Mar 2021 17:05:21
User entered 'USA-US104-2021-mRNA-1273-P301000012'	System	04 Mar 2021 17:05:17
User entered 'New'	(b) (4), (b) (6)	04 Mar 2021 17:05:17

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'Per MM, please split and record each condition separately and confirm if chest pain is musculoskeletal or cardiac related' (Site from DM).		08 Apr 2021 12:10:44
User closed query 'PV Query: The event term 'chest pain with shortness of breath' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).		07 Apr 2021 16:43:15
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:26:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 19:26:15
Query 'Per MM, please split and record each condition separately and confirm if chest pain is musculoskeletal or cardiac related' answered with 'updated per medical records' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 19:25:20
Query 'PV Query: The event term 'chest pain with shortness of breath' contains multiple event terms. Please consider separating them into separate events.' answered with 'corrected' (Site from Safety).		06 Apr 2021 19:25:06
Data point term sent to Coder	System	06 Apr 2021 19:25:06
Coding entries removed.	(b) (4), (b) (6)	06 Apr 2021 19:24:58
User entered 'Chest pain' reason for change: Data Entry Error		06 Apr 2021 19:24:58
User opened query 'Per MM, please split and record each condition separately and confirm if chest pain is musculoskeletal or cardiac related' (Site from DM).		26 Mar 2021 13:09:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:54:41
Data point term sent to Coder	System	18 Mar 2021 11:54:15
Coding entries removed.	Diana Toney (b) (4) (b) (4)	18 Mar 2021 11:53:21
User entered 'Shortness of Breath' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 11:53:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Short of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:07:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:07:56
User opened query 'PV Query: The event term 'chest pain with shortness of breath' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:30:24
Data point term sent to Coder	System	05 Mar 2021 19:34:48
Coding entries removed.	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:34:04
User entered 'CHEST PAIN WITH SHORT OF BREATH' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:34:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 19:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 19:59:44
Data point term sent to Coder	System	03 Mar 2021 19:59:16
User entered 'SHORTNESS OF BREATH'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		07 Apr 2021 16:43:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'COVID testing not completed in hospital' (Site from Safety).		06 Apr 2021 19:40:16
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		11 Mar 2021 14:28:46
User closed query 'Data is required. Please complete.' (Site from System).		05 Mar 2021 19:34:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 19:34:04
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:34:04
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:58:24
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '01 Mar 2021'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 11:53:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 11:53:21
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 11:53:21
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:37:25
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:37:25
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:34:04
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: The event, shortness of breath, was reported with the end date of 03 Mar 2021. However, the outcome was reported as recovering/resolving. Please consider updating outcome to recovered/resolved. ' (Site from Safety).		07 Apr 2021 16:43:08
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		07 Apr 2021 16:43:04
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).		06 Apr 2021 20:14:41
Query 'PV Query: The event, shortness of breath, was reported with the end date of 03 Mar 2021. However, the outcome was reported as recovering/resolving. Please consider updating outcome to recovered/resolved. ' answered with 'updated' (Site from Safety).		06 Apr 2021 20:14:31
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:13:04
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Apr 2021 20:13:04
User opened query 'PV Query: The event, shortness of breath, was reported with the end date of 03 Mar 2021. However, the outcome was reported as recovering/resolving. Please consider updating outcome to recovered/resolved. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:17:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 11:53:21
User entered '03 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 11:53:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:29:11
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 19:37:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Mar 2021 19:37:08
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Mar 2021 19:37:08
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 19:37:08
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:37:08
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Mar 2021 19:36:37
User entered '03 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:34:04
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).		07 Apr 2021 16:40:26
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'required hospitalization as listed below' (Site from Safety).		06 Apr 2021 20:14:17
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	05 Mar 2021 19:35:19
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 18:06:36
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	03 Mar 2021 19:58:24
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		05 Mar 2021 19:36:08
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		05 Mar 2021 19:36:08
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Mar 2021 19:35:19
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		05 Mar 2021 19:35:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 19:35:19
User entered '1' reason for change: Data Entry Error	Diana Toney (b) (4)	05 Mar 2021 19:35:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	05 Mar 2021 19:34:04
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '01 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	05 Mar 2021 19:34:04
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: Please confirm hospital discharge date as lab results are provided for 04 Mar 2021' (Site from Safety).		07 Apr 2021 16:41:25
Query 'PV Query: Please confirm hospital discharge date as lab results are provided for 04 Mar 2021' answered with 'hospital DC date per DC summary is 3/3/21' (Site from Safety).		06 Apr 2021 20:15:19
User opened query 'PV Query: Please confirm hospital discharge date as lab results are provided for 04 Mar 2021' (Site from Safety).		11 Mar 2021 14:30:55
User entered '03 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	05 Mar 2021 19:34:04
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4)	05 Mar 2021 19:36:08
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

US3222524

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		28 Apr 2021 15:44:52
User closed query 'Per DM guidance below, please revise source to Not Applicable.' (Site from CRA).		28 Apr 2021 15:44:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
	(b) (4)	
Query 'Per DM guidance below, please revise source to Not Applicable.' answered with 'CORRECTED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	22 Apr 2021 12:23:20
	(b) (4)	
User opened query 'Per DM guidance below, please revise source to Not Applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:41:32
DataPoint Un-verified.		21 Apr 2021 15:40:45
DataPoint Verified.		21 Apr 2021 15:40:36
User closed query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' (Site from Safety).		15 Apr 2021 13:18:43
Query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' answered with 'UPDATED TO NOT APPLICABLE' (Site from Safety).	douglas winter (b) (4)	14 Apr 2021 18:27:05
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Apr 2021 18:26:54
	(b) (4)	
User opened query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:15:51
User entered 'None (NONE)'	Diana Toney (b) (4)	03 Mar 2021 19:58:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
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).		07 Apr 2021 16:42:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).		06 Apr 2021 20:15:28
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).		11 Mar 2021 14:29:50
User entered 'I'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		28 Apr 2021 15:44:57
User closed query 'This is not entered in source AE log. If correct, please enter there.' (Site from CRA).		28 Apr 2021 15:44:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
	(b) (4)	
Query 'This is not entered in source AE log. If correct, please enter there.' answered with 'CORRECTED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	22 Apr 2021 12:25:08
	(b) (4)	
User opened query 'This is not entered in source AE log. If correct, please enter there.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:42:05
DataPoint Un-verified.		21 Apr 2021 15:40:53
DataPoint Verified.		21 Apr 2021 15:40:36
User entered '1' reason for change: Data Entry Error		06 Apr 2021 20:05:17
User entered '0'	Diana Toney (b) (4)	03 Mar 2021 19:58:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		28 Apr 2021 15:44:59
User closed query 'This is not entered in source AE log. If correct, please enter there.' (Site from CRA).		28 Apr 2021 15:44:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Query 'This is not entered in source AE log. If correct, please enter there.' answered with 'CORRECTED TO MATCH SOURCE' (Site from CRA).	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:25:11
User opened query 'This is not entered in source AE log. If correct, please enter there.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:41:54
DataPoint Un-verified.		21 Apr 2021 15:40:40
DataPoint Verified.		21 Apr 2021 15:40:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).		07 Apr 2021 16:42:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		06 Apr 2021 20:13:04
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'patient dc from hospital on 3/3/21 cleared by cardiology. Patient passed away on 3/16/21' (Site from Safety).		06 Apr 2021 20:02:48
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).		11 Mar 2021 14:29:33
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:36:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 19:36:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	05 Mar 2021 19:36:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:58:24
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		07 Apr 2021 16:42:34
User closed query 'PV Query: As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from none to not applicable.' (Site from Safety).		07 Apr 2021 16:42:25
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'patient has history of cardiac disease, pacemaker, and a fib' (Site from Safety).		06 Apr 2021 19:45:56
Query 'PV Query: As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from none to not applicable.' answered with 'none' (Site from Safety).		06 Apr 2021 19:44:12
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		11 Mar 2021 14:30:04
User opened query 'PV Query: As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from none to not applicable.' (Site from Safety).		11 Mar 2021 14:28:27
User entered 'TODAY AT 1230 PT WIFE STATED AT HER APPOINTMENT THAT THE SUBJECT IS CURRENTLY IN THE HOSPITAL WENT IN ON 01MAR2021 FOR SHORTNESS OF BREATH AND IS STILL CURRENTLY IN DELAND HOSPITAL. WE WILL SEND A RECORD RELEASE FOR RECORDS'	Diana Toney (b) (4) (b) (4)	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	03 Mar 2021 19:58:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '0'	System	05 Mar 2021 19:36:08

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
Reviewed for Safety.		19 Mar 2021 13:02:25
User entered 'USA-US104-2021-mRNA-1273-P301000012'		18 Mar 2021 13:57:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User coded data point as SOC: Investigations, HLG: Toxicology and therapeutic drug monitoring, HLT: Therapeutic drug monitoring analyses, PT: Anticoagulation drug level above therapeutic, LLT: Supratherapeutic INR - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:26:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:26:32
Data point term sent to Coder	System	18 Mar 2021 21:13:14
Coding entries removed.	Diana Toney (b) (4) (b) (4)	18 Mar 2021 21:12:32
User entered 'Supra therapeutic INR' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 21:12:32
User coded data point as SOC: Cardiac disorders, HLG: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:51:45
Data point term sent to Coder	System	18 Mar 2021 11:51:14
User entered 'Congestive Heart Failure' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 11:50:25
Data point term sent to Coder	System	17 Mar 2021 10:40:04
User entered 'unkown'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '12 Mar 2021'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '12 Mar 2021'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Grade 4 (Grade 4)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 17:32:56
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' answered with 'autopsy not performed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:50:19
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:16:34
User entered 'I'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		19 Mar 2021 08:53:42
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'reconciled' (Site from System).	Diana Toney (b) (4) (b) (4)	18 Mar 2021 21:14:22
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Mar 2021 21:13:37
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Mar 2021 21:13:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Mar 2021 21:13:37
User entered '1' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 21:13:37
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	18 Mar 2021 21:12:32
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '12 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	18 Mar 2021 21:12:32
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '12 Mar 2021' reason for change: Data Entry Error	Diana Toney (b) (4)	18 Mar 2021 21:12:32
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		28 Apr 2021 15:45:28
User closed query 'Per DM guidance below, please revise source to Not Applicable.' (Site from CRA).		28 Apr 2021 15:45:25
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
	(b) (4)	
Query 'Per DM guidance below, please revise source to Not Applicable.' answered with 'CORRECTED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	22 Apr 2021 12:19:53
	(b) (4)	
User opened query 'Per DM guidance below, please revise source to Not Applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:43:18
DataPoint Un-verified.		21 Apr 2021 15:43:11
DataPoint Verified.		21 Apr 2021 15:40:36
User closed query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' (Site from Safety).		15 Apr 2021 13:19:05
Query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' answered with 'UPDATED TO NOT APPLICABLE' (Site from Safety).	douglas winter (b) (4)	14 Apr 2021 18:27:38
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Apr 2021 18:27:26
	(b) (4)	
User opened query 'PV Query: This still has not been addressed. As the last dose of study drug was given on 14 Feb 2021, please update the action taken with study drug from None to Not Applicable. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:15:03
User entered 'None (NONE)'	Diana Toney (b) (4)	17 Mar 2021 10:39:12
	(b) (4)	

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered 'I'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered '0'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'Per DM CLR: Outcome = Fatal however there is no entry in End of Study page. Please add an entry and its details in the End of Study eCRF as appropriate. Otherwise, please provide clarification.' (Site from DM).		08 Apr 2021 12:11:31
Query 'Per DM CLR: Outcome = Fatal however there is no entry in End of Study page. Please add an entry and its details in the End of Study eCRF as appropriate. Otherwise, please provide clarification.' answered with 'updated' (Site from DM).		06 Apr 2021 20:56:00
User opened query 'Per DM CLR: Outcome = Fatal however there is no entry in End of Study page. Please add an entry and its details in the End of Study eCRF as appropriate. Otherwise, please provide clarification.' (Site from DM).		05 Apr 2021 13:23:21
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 10:39:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 10:39:32
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:32
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 10:39:12
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:40:36
User entered empty.	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User closed query 'PV Query: This still has not been addressed. Please confirm if gastrointestinal bleed/congestive heart failure should be reported as SAEs. If not, please clarify. ' (Site from Safety). User signature succeeded.	(b) (4)	26 Apr 2021 20:42:25
	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Query 'PV Query: This still has not been addressed. Please confirm if gastrointestinal bleed/congestive heart failure should be reported as SAEs. If not, please clarify. ' answered with 'ADDED 2 MORE SAE'S' (Site from Safety). DataPoint Verified.	douglas winter (b) (4) (b) (4)	23 Apr 2021 21:27:56
	(b) (4), (b) (6)	21 Apr 2021 15:40:36
User closed query 'PV Query: Recent query response stated 'Patient passed away on 3/16/21' but event supra therapeutic INR was reported as fatal on 12Mar2021. Please confirm date subject passed away. ' (Site from Safety).	(b) (4)	15 Apr 2021 13:19:09
Query 'PV Query: Recent query response stated 'Patient passed away on 3/16/21' but event supra therapeutic INR was reported as fatal on 12Mar2021. Please confirm date subject passed away. ' answered with 'PATIENT EXPIRED ON 12/MAR/2021' (Site from Safety).	douglas winter (b) (4) (b) (4)	14 Apr 2021 18:33:12
User opened query 'PV Query: Recent query response stated 'Patient passed away on 3/16/21' but event supra therapeutic INR was reported as fatal on 12Mar2021. Please confirm date subject passed away. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:15:34
User opened query 'PV Query: This still has not been addressed. Please confirm if gastrointestinal bleed/congestive heart failure should be reported as SAEs. If not, please clarify. ' (Site from Safety).		13 Apr 2021 13:14:51
User closed query 'PV Query: Please review if gastrointestinal bleed/congestive heart failure should be reported as SAEs ' (Site from Safety).		07 Apr 2021 17:33:07

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please review if gastrointestinal bleed/congestive heart failure should be reported as SAEs ' answered with 'GI bleed, CHF, and supratherapeutic INR documented as cause of death on death certificate' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:57:32
User opened query 'PV Query: Please review if gastrointestinal bleed/congestive heart failure should be reported as SAEs ' (Site from Safety).		25 Mar 2021 18:16:48
User entered 'SUBJECT US3222524 WAS TAKEN BY AMBULANCE ON 12MAR2021. WIFE STATES SUBJECT EXPIRED AT THE HOSPITAL, WE HAVE REQUESTED RECORDS AND WE HAVE BEEN PROVIDED A DEATH CERTIFICATE PRIMARY CAUSE IS SUPRA THERAPEUTIC INR SECONDARY GASTROINTESTINAL BLEED AND THIRD CAUSE IS CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	18 Mar 2021 21:12:32
User entered 'Subject US3222524 was taken by ambulance on 12mar2021. Wife states subject expired at the hospital, we will at this time request records and will update when more information is available.'	Diana Toney (b) (4) (b) (4)	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	17 Mar 2021 10:39:12

US3222524

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:54:44
User entered 'USA-US104-2021-mRNA-1273-P301000012'		26 Apr 2021 14:54:34

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: Gastrointestinal bleed - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:29:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:29:02
Data point term sent to Coder	System	23 Apr 2021 21:27:48
User entered 'GASTROINTESTINAL BLEED'	douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Grade 4 (Grade 4)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 21:27:08
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).		23 Apr 2021 21:27:08
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 21:27:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 21:26:51
User entered '0'	douglas winter (b) (4)	23 Apr 2021 21:26:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Fatal (FATAL)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'SECONDARY SAE TO SAE # 2 SUBJECT US3222524 WAS TAKEN BY AMBULANCE ON 12MAR2021. WIFE STATES SUBJECT EXPIRED AT THE HOSPITAL, WE HAVE REQUESTED RECORDS AND WE HAVE BEEN PROVIDED A DEATH CERTIFICATE PRIMARY CAUSE IS SUPRA THERAPEUTIC INR SECONDARY GASTROINTESTINAL BLEED AND THIRD CAUSE IS CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 21:29:10
User entered 'SECONDARY SAE TO SUBJECT US3222524 WAS TAKEN BY AMBULANCE ON 12MAR2021. WIFE STATES SUBJECT EXPIRED AT THE HOSPITAL, WE HAVE REQUESTED RECORDS AND WE HAVE BEEN PROVIDED A DEATH CERTIFICATE PRIMARY CAUSE IS SUPRA THERAPEUTIC INR SECONDARY GASTROINTESTINAL BLEED AND THIRD CAUSE IS CONGESTIVE HEART FAILURE'	douglas winter (b) (4)	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered 'I'	System	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '0'	System	23 Apr 2021 21:26:51

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:55:19
User entered 'USA-US104-2021-mRNA-1273-P301000012'	(b) (4), (b) (6)	26 Apr 2021 14:55:14

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as SOC: Cardiac disorders, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:34:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:34:07
Data point term sent to Coder	System	23 Apr 2021 21:32:54
User entered 'CONGESTIVE HEART FAILURE'	douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Grade 4 (Grade 4)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	23 Apr 2021 21:32:18
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	23 Apr 2021 21:32:18
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Apr 2021 21:32:18
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 21:32:18
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 21:31:59
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	23 Apr 2021 21:31:59
User entered 'No (N)'	douglas winter (b) (4)	23 Apr 2021 21:31:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 21:32:33
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).		23 Apr 2021 21:32:33
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 21:32:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 21:31:59
User entered '0'	douglas winter (b) (4)	23 Apr 2021 21:31:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Fatal (FATAL)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'SECONDARY SAE. SEE PRIMARY SAE #2 SUBJECT US3222524 WAS TAKEN BY AMBULANCE ON 12MAR2021. WIFE STATES SUBJECT EXPIRED AT THE HOSPITAL, WE HAVE REQUESTED RECORDS AND WE HAVE BEEN PROVIDED A DEATH CERTIFICATE PRIMARY CAUSE IS SUPRA THERAPEUTIC INR SECONDARY GASTROINTESTINAL BLEED AND THIRD CAUSE IS CONGESTIVE HEART FAILURE'	douglas winter (b) (4)	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	23 Apr 2021 21:32:18
User entered '0'	System	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered 'I'	System	23 Apr 2021 21:31:59

US3222524

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '0'	System	23 Apr 2021 21:31:59

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	26 Oct 2020 19:47:52
User entered 'No (N)'	(b) (4)	
	Albert Garcia (b) (4)	09 Oct 2020 16:56:48
	(b) (4)	

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per CDM: Please note, CM #1 and CM #2 has duplicate data. please review both the CM entries and update accordingly to avoid overlapping/duplicate data, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 09:44:32
Query 'Per CDM: Please note, CM #1 and CM #2 has duplicate data. please review both the CM entries and update accordingly to avoid overlapping/duplicate data, else clarify.' answered with 'INACTIVATED CONMED #2 DUPLICATE' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Apr 2021 18:48:59
User opened query 'Per CDM: Please note, CM #1 and CM #2 has duplicate data. please review both the CM entries and update accordingly to avoid overlapping/duplicate data, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:50:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:13:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:13:32
Data point term sent to Coder	System	26 Oct 2020 20:12:47
User entered 'GABAPENTIN'	Alicia Cevera (b) (4) (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	09 Apr 2021 14:41:05
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 'updated' (Site from DM).		06 Apr 2021 20:25:48
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).		22 Jan 2021 07:53:01
User entered 'NEUROPATHY'	Alicia Cevera (b) (4) (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '300'	Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'three times daily (TID)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	30 Oct 2020 11:37:47
User entered empty; reason for change Data Entry Error	System	30 Oct 2020 11:37:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Alicia Cevera (b) (4)	30 Oct 2020 11:37:47
User entered 'UN UNK UN' (non-conformant).	(b) (4)	26 Oct 2020 20:12:13
	System	26 Oct 2020 20:12:13
	Alicia Cevera (b) (4)	26 Oct 2020 20:12:13
	(b) (4)	

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '3'	System	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	26 Oct 2020 20:12:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:28:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:28:15
Data point term sent to Coder	System	30 Oct 2020 19:38:34
User entered 'acetaminophen er'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'back pain'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '650'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'as needed (PRN)'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:37:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:38:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 19:38:56
Data point term sent to Coder User entered 'amlodipine'	System Alicia Cevera (b) (4)	30 Oct 2020 19:38:35 30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'hypertension'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '5'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:38:24

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	30 Oct 2020 19:41:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:41:04
Data point term sent to Coder User entered 'atorvastatin'	System Alicia Cevera (b) (4)	30 Oct 2020 19:39:36 30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'hypercholesterolemia'	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '40'	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:39:03

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:22:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:22:10
Data point term sent to Coder	System	30 Oct 2020 19:40:39
User entered 'calcium citrate w/vitamin d'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'supplement'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '2'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:40:20

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:42:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:42:55
Data point term sent to Coder	System	30 Oct 2020 19:41:40
User entered 'citalopram'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'depression'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '40'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:40:53

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:20:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:20:09
Data point term sent to Coder	System	30 Oct 2020 19:42:41
User entered 'Colace'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'supplement'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'as needed (PRN)'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:41:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 20:27:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 20:27:26
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Apr 2021 20:26:33 06 Apr 2021 20:25:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 19:43:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 19:43:56
Data point term sent to Coder User entered 'coumadin'	System Alicia Cevera (b) (4)	30 Oct 2020 19:42:41 30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per DM CLR: The indication signifies SUPPORT. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:16:55
Query 'Per DM CLR: The indication signifies SUPPORT. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'corrected' (Site from DM).		06 Apr 2021 20:25:22
User opened query 'Per DM CLR: The indication signifies SUPPORT. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).		22 Jan 2021 07:53:47
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'blood thinner' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:25:15
User entered 'cardiac support'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '5'	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:42:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Oct 2020 11:09:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:09:18
Data point term sent to Coder	System	30 Oct 2020 19:43:45
User entered 'hydralazine'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'coronary artery disease'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '25'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:43:42

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 09:47:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 09:47:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Apr 2021 20:28:37
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:00:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:00:08
Data point term sent to Coder	System	30 Oct 2020 19:44:46
User entered 'prednisone'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate condition recorded' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:31:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate condition recorded' answered with 'corrected' (Site from DM).		06 Apr 2021 20:28:09
User entered 'low corticosteroid level' reason for change: Data Entry Error		06 Apr 2021 20:28:02
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate condition recorded' (Site from DM).		22 Jan 2021 07:54:05
User entered 'pituitary gland'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '10'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:44:37

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:47:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:47:06
Data point term sent to Coder	System	30 Oct 2020 19:45:47
User entered 'iron'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'supplement'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '65'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:45:11

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:00:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:00:14
Data point term sent to Coder	System	30 Oct 2020 19:46:48
User entered 'lactulose'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'intermittent constipation'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '10'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'g (g)'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:46:40

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 04:43:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 04:43:31
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Apr 2021 20:29:37 06 Apr 2021 20:29:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:04:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:04:11
Data point term sent to Coder User entered 'nitroglycerine'	System Alicia Cevera (b) (4)	30 Oct 2020 19:47:50 30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'atrial fibrillation'	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0.4'	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'as needed (PRN)'	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	09 Apr 2021 15:17:57
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).		06 Apr 2021 20:29:22
User entered 'Other (OTHER)' reason for change: Data Entry Error		06 Apr 2021 20:29:14
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).		22 Jan 2021 07:54:18
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'sublingual' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:29:14
User entered empty.	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	03 Nov 2020 17:52:35
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	30 Oct 2020 19:47:47
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47
	(b) (4)	

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	03 Nov 2020 17:52:35
User entered '0'	(b) (4)	
	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47
	(b) (4)	

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	30 Oct 2020 19:47:47

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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.	Coder Import (b) (4)	30 Oct 2020 19:50:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:50:59
Data point term sent to Coder	System	30 Oct 2020 19:50:08
User entered 'pantoprazole'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'gastroesophageal reflux disease'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '40'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:49:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX WITH VITAMIN C, PRODUCT: ASCORBIC ACID;VITAMIN B COMPLEX, PRODUCTSYNONYM: SUPER B COMPLEX WITH VITAMIN C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:26:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:26:09
Data point term sent to Coder	System	30 Oct 2020 19:51:11
User entered 'super B/C'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'supplement'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:50:13

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 20:08:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 20:08:02
Data point term sent to Coder	System	30 Oct 2020 19:52:13
User entered 'tamsulosin'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	09 Apr 2021 15:19:08
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 'updated' (Site from DM).		06 Apr 2021 20:30:03
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).		22 Jan 2021 07:54:32
User entered 'benign prostatic hypertrophy'	Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0.4'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:51:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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: VITAMIN D 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:53:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:53:56
Data point term sent to Coder	System	30 Oct 2020 19:53:14
User entered 'vitamin d-3'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'supplement'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '1000'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'IU (IU)'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	Alicia Cevera (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	30 Oct 2020 19:52:17

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:19:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:19:26
Data point term sent to Coder User entered 'hydrocodone'	System (b) (4), (b) (6)	06 Apr 2021 20:19:01 06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'pain'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '325/10'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:19:01
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:19:01
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:19:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Apr 2021 20:18:55
User entered '03 Mar 2021' (non-conformant).	System	06 Apr 2021 20:18:55
	(b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:18:55

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:23:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	06 Apr 2021 20:23:28
Data point term sent to Coder	System	06 Apr 2021 20:22:06
User entered 'amlodipine'	(b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '35'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:21:41
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:21:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:21:36
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '803 (803)'	System	06 Apr 2021 20:21:36

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	06 Apr 2021 20:24:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:24:22
Data point term sent to Coder	System	06 Apr 2021 20:23:10
User entered 'aspirin'	(b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'blood thinner'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '81'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:22:54
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:22:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:22:48
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	06 Apr 2021 20:22:48

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:27:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:27:26
Data point term sent to Coder	System	06 Apr 2021 20:25:13
User entered 'donepezil'	(b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'dementia'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '10'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:24:41
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:24:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:24:33
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	06 Apr 2021 20:24:33

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:34:17
Data point term sent to Coder	System	06 Apr 2021 20:33:40
User entered 'finasteride'	(b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'BPH'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '5'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:34:41
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:34:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:33:14
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	06 Apr 2021 20:33:14

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	06 Apr 2021 20:37:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:37:35
Data point term sent to Coder	System	06 Apr 2021 20:36:42
User entered 'metoprolol'	(b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '25'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:36:30
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:36:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:36:25
User entered ' Mar 2021' (non-conformant).	System	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	06 Apr 2021 20:36:25

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 10:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:03:38
Data point term sent to Coder	System	06 Apr 2021 20:39:44
User entered 'ropinerole'	(b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'tremors'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:38:49
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:38:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:38:44
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	06 Apr 2021 20:38:44

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 20:42:36
Data point term sent to Coder	System	06 Apr 2021 20:41:46
User entered 'sildenafil'	(b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'erectile dysfunction'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '100'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:41:15
User entered '03 Mar 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:41:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:41:10
User entered ' Mar 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered empty.	System	06 Apr 2021 20:41:10

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:24:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:24:49
Data point term sent to Coder	System	22 Apr 2021 11:59:22
User entered 'WARFARIN'	douglas winter (b) (4)	22 Apr 2021 11:58:38
	(b) (4)	

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'A-FIB'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '5'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '03 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	22 Apr 2021 11:58:38

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:02:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:02:57
Data point term sent to Coder	System	22 Apr 2021 12:02:23
User entered 'TAMSULOSIN'	douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'BPH'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0.4'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '03 Feb 2021'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	22 Apr 2021 12:02:12

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
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)	22 Apr 2021 12:06:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 12:06:10
Data point term sent to Coder	System	22 Apr 2021 12:05:25
User entered 'FUROSEMIDE'	douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '03 Mar 2021'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '804 (804)'	System	22 Apr 2021 12:04:31

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:08:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:08:56
Data point term sent to Coder User entered 'ALENDRONATE'	System douglas winter (b) (4)	22 Apr 2021 12:08:26 22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'OSTEOPOROSIS'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '35'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'every week (QS)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '03 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '1'	System	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '803 (803)'	System	22 Apr 2021 12:07:49

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:05:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:42:56
User entered 'Yes (Y)' reason for change: Data Entry Error		06 Apr 2021 20:42:56
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 19:59:46
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	09 Oct 2020 16:56:43

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:43:58

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Chest XR'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:43:58

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:43:58

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:43:58

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:46:55

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'echocardiogram'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:46:55

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:46:55

US3222524

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:46:55

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:54:52
User entered 'Death (DEATH)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:54:52
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	06 Apr 2021 20:54:42
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:54:42
User entered 'Death (DEATH)'		06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	06 Apr 2021 20:55:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:55:02
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:54:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:54:42
User entered 'Death SAE DOCUMENTED SUPRATHERAPEUTIC INR' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:54:42
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:53:52
User entered 'SAE documented suprathapeutic INR'	(b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:57

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:24
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:53:52

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered '04/Mar/2021 17:05'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 19:35:19
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
User entered '08/Mar/2021 08:07'	System	08 Mar 2021 13:07:24

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
User entered 'I'		08 Mar 2021 13:07:24

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 19:35:19
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
User entered '18/Mar/2021 09:58'	System	18 Mar 2021 13:58:28

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
User entered 'I'		18 Mar 2021 13:58:28

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
User entered '19/Mar/2021 08:02'	System	19 Mar 2021 13:03:03

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:11:25
User entered 'I'		19 Mar 2021 13:03:03

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
User entered '19/Mar/2021 08:11'	System	19 Mar 2021 13:11:47

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		07 Apr 2021 16:45:34
User entered 'I'		19 Mar 2021 13:11:47

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
User entered '07/Apr/2021 12:45'	System	07 Apr 2021 16:45:16

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		07 Apr 2021 16:45:34
User entered 'I'		07 Apr 2021 16:45:16

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:39:32
User entered '15/Apr/2021 06:17'	System	15 Apr 2021 13:17:53

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:59:08
DataPoint Verified.		21 Apr 2021 15:39:32
User entered 'I'		15 Apr 2021 13:17:53

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'USA-US104-2021-MRNA-1273-P301000012'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Yes (Y)'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Un-reviewed for Safety.	(b) (4)	
User entered 'Yes (Y)'	System	05 Mar 2021 19:35:19
Reviewed for Safety.	System	05 Mar 2021 19:35:19
	(b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'No (N)'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Bruce'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Teresa'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Rankin'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Becker'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '6550 Mapleridge Street'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered 'Deland'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered 'Houston'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:43:07
Reviewed for Safety.		19 Mar 2021 13:02:48
Un-reviewed for Safety.	System	18 Mar 2021 13:57:16
Signature has been broken.	System	18 Mar 2021 13:57:16
User entered '32720'	System	18 Mar 2021 13:57:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:05:46
User entered '77081'	System	04 Mar 2021 17:05:17

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
DataPoint Verified.		15 Apr 2021 12:43:07
Reviewed for Safety.		08 Mar 2021 13:07:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:26:28
User entered 'US'	(b) (4) System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User entered '8'	System	26 Apr 2021 14:59:44
User entered '7'	System	15 Apr 2021 13:17:53
User entered '6'	System	07 Apr 2021 16:45:16
User entered '5'	System	19 Mar 2021 13:11:47
User entered '4'	System	19 Mar 2021 13:03:03
User entered '3'	System	18 Mar 2021 13:58:28
User entered '2'	System	08 Mar 2021 13:07:24
User entered '1'	System	04 Mar 2021 17:05:51

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:05:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered '26/Apr/2021 10:59'	(b) (4) System	26 Apr 2021 14:59:44

US3222524

Folder: SAE USA-US104-2021-MRNA-1273-P301000012

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:05:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:46:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:02:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:59:44