

US3112164 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:15:39

All time stamps listed in this document are displayed in GMT

US3112164

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:09:05

Generated On: 09 Jun 2021 15:15:39

Participant ID

US3112164

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

US3112164

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3112164

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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

US3112164

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3112164

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Were any significant conditions reported?

Yes ☒

No ☐

US3112164

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Condition	HYPERCHOLESTEROLERMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3112164

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Condition	BENIGN PROSTRATE HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3112164

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3112164

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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)	

US3112164

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3112164

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:20
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	168 lb
BMI (<i>xxx.x</i>)	26.36754 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)	

US3112164

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3112164

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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 False

Resides in Nursing Home or Assisted Living Facility False

US3112164

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:56:15

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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

What was the participant's randomization number? 184856

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 ☒

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Height	ND - Not Done
Weight	ND - Not Done

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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)	10 AUG 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:20
Temperature (xxx.x)	98.1 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)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:20
Temperature (xxx.x)	96.8 F
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)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	064 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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.

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 10:49

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

What was the frequency of the study treatment dosing? ONCE

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

US3112164

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	09:57 (24 HR)
Collection date and time (derived)	10 AUG 2020 09:57

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	10 AUG 2020 09:50
Nasopharyngeal Swab 2	No		

US3112164

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 11:24

PC Open Date & Time

10 AUG 2020 11:09

PC Close Date & Time

10 AUG 2020 13:39

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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 96.8 °F

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

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

PC Time Stamp	10 AUG 2020 14:34
PC Open Date & Time	10 AUG 2020 14:34
PC Close Date & Time	11 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

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

97.4 °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

11 AUG 2020 12:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:01

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 18:38

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

14 AUG 2020 13:51

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 13:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:25

PC Open Date & Time

10 AUG 2020 11:09

PC Close Date & Time

10 AUG 2020 13:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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

10 AUG 2020 14:35

PC Open Date & Time

10 AUG 2020 14:34

PC Close Date & Time

11 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:01

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:38

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 13:51

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 13:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

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 ☐

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:25
PC Open Date & Time	10 AUG 2020 11:09
PC Close Date & Time	10 AUG 2020 13:39

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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 ☐

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 14:36
PC Open Date & Time	10 AUG 2020 14:34
PC Close Date & Time	11 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

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 ☒

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2595

EAB) (1725)

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

53 of 2595

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

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 ☒

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 13:52
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

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)

57 of 2595

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 13:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

59 of 2595

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112164

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:40:45

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:40:45

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:40:22

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:40:22

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:40:22

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:40:22

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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)	08 SEP 2020
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:27
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:47
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 10:16 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 10:16

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

What was the frequency of the study treatment dosing? ONCE

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

US3112164

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	8 SEP 2020 09:40

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:33	8 SEP 2020 09:33
Nasopharyngeal Swab 2	No		

US3112164

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 10:46

PC Open Date & Time

08 SEP 2020 10:36

PC Close Date & Time

08 SEP 2020 13:06

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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 97.8 °F

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

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

PC Time Stamp	09 SEP 2020 06:48
PC Open Date & Time	08 SEP 2020 14:01
PC Close Date & Time	09 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:37

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

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

97.2 °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 12:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

12 SEP 2020 12:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

13 SEP 2020 13:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 10:46

PC Open Date & Time

08 SEP 2020 10:36

PC Close Date & Time

08 SEP 2020 13:06

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 06:48

PC Open Date & Time

08 SEP 2020 14:01

PC Close Date & Time

09 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 19:37

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 13:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

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 ☐

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:47
PC Open Date & Time	08 SEP 2020 10:36
PC Close Date & Time	08 SEP 2020 13:06

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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 ☐

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 06:49
PC Open Date & Time	08 SEP 2020 14:01
PC Close Date & Time	09 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

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 ☒

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

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 ☒

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:37
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2595

EAB) (1725)

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

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)

101 of 2595

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

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 ☒

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:21
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

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)

105 of 2595

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112164

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:40:45

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:40:45

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

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 _____

US3112164

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:56
Temperature (xxx.x)	98.2 F
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112164

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3112164

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	11:20 (24 HR)
Collection date and time (derived)	28 OCT 2020 11:20

US3112164

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:55:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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 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	10 OCT 2020 07:01:51
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	17 OCT 2020 09:48:11
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 15:48:30

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 12:04:26
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 08:34:38
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 07:44:25

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 07:08:17

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 14:53:26

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 06:59:16

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 07:45:45

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 07:35:18

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 08:14:18

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 JAN 2021 07:11:56
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 07:35:56
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:46:09

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 17:59:23

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 07:33:28

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 12:21:41

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 09:16:35
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 17:34:13

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 20:53:27

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 07:02:12

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 09:00:31

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 08:16:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 07:43:18

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 08:25:31

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 07:06:41

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 07:25:17

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 06:48:53

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2021 00:01
Patient Cloud Close Date & Time	13 JUN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 376

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°F/38°C)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

Patient Cloud Open Date & Time	24 NOV 2021 00:01
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Patient Cloud Close Date & Time	28 NOV 2021 23:59
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US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3112164

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:15:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 19:40:00

US3112164

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:47:37

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:47:37

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	9:00 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 9:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112164

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

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.

US3112164

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	8 MAR 2021 09:20

US3112164

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 22:53:06

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 APR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:53:06

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112164

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:15:39

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"/>

US3112164

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:15:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	5 JAN 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 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>)	5 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

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Height	ND - Not Done
Weight	ND - Not Done
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)	5 JAN 2021
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 09:42
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Height	ND - Not Done
Weight	ND - Not Done
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)	5 JAN 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 10:50
Temperature (xxx.x)	98.3 F
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)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

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) 5 JAN 2021

What was the treatment time? (00:00-23:59) 10:19 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 10:19

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

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	5 JAN 2021
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Collection time (00:00-23:59)	10:00 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	5 JAN 2021 10:00
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US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	09:54
Collection Date and Time (derived)	5 JAN 2021 09:54

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3112164

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

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)	2 FEB 2021
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 09:31
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

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)	2 FEB 2021
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:24
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3112164

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112164

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

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) 2 FEB 2021

What was the treatment time? (00:00-23:59) 09:53 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 09:53

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

US3112164

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112164

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112164

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	9:00 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 9:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112164

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

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.

US3112164

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	8 MAR 2021
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Collection time (00:00-23:59)	09:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 MAR 2021 09:20
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US3112164

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:22:49

Generated On: 09 Jun 2021 15:15:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

AEID	USA-US062-2020-MRNA-1273-P30 1000002
Adverse event	SEVERE CORONARY ARTERY DISEASE
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)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	24 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	344 of 2595

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

PT. STATES HE HAD GONE IN
FOR ELECTIVE CARIAC CATH
TO EVAL EXERTIONAL SX'S
(SOB, CHEST TIGHTNESS). PT.
STATES HAS HAD SX'S FOR
ATLEAST 6 MONTHS. STATES
DID NOT SHARE THIS WITH
SITE STAFF AS HE DID NO
THINK MUCH OF IT. STATES
WENT I AND ON ANGIO HAD
SIG DISEASE OF LEFT MAIN
AND LAD. AT THAT TIME CABG
X3 PERFORMED. WAS
HOSPITALIZED AT SHARP
MEMORIAL FROM 16 SEP 2020 -
24 SEP 2020. NOW AT HOME
DOING MUCH BETTER.

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

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

AEID	USA-US062-2020-MRNA-1273-P30 1000002
Adverse event	PLEURAL EFFUSION
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)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	04 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

347 of 2595

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:22:48

Generated On: 09 Jun 2021 15:15:39

PATIENT PRESENTED AT
HOSPITAL FOR POTENTIAL
COMPLICATIONS WITH PRIOR
CABG X3, DIAGNOSIS OF LEFT
PLUERAL EFFUSION. CHEST
TUBE PLACED AND DRAINED
ON 02OCT2020, MONITORED
UNTIL DISCHARGE ON
04OCT2020. PRESCRIPTION OF
LEVAQUIN AS ADDITIONAL
TREATMENT / PROPHYLAXIS.

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

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication ATENOLOL XS

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication NOROXIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS PAIN RELIEF

Dose per administration 15

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
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"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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)

361 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication PLEURAL EFFUSION

Dose per administration 750

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

Q48HR

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

365 of 2595

EAB) (1725)

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC EVENT
PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication CAD

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)

369 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication BUMEX

Prophylaxis Yes ☐
No ☒

Indication SEVERE CORONARY ARTERY DISEASE

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication ZETIA

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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)

375 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 400

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)

377 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

381 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration .3

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)

383 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CARPAL TUNNEL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
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"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MCG

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)

387 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SEVERE CORONARY ARTERY DISEASE

Dose per administration 10

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MEQ

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN MANAGEMENT

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

Q4HR PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication SEVERE CORONARY ARTERY DISEASE

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

Name of Medication EXCEDRIN(ACETAMINOPHEN,
ASPIRIN, CAFFEINE)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 22:53:05

Generated On: 09 Jun 2021 15:15:39

	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)	11 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:09:06

Generated On: 09 Jun 2021 15:15:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 SEP 2020	CABG X3	Adverse Event	
02 OCT 2020	LEFT CHEST TUBE	Adverse Event	
18 SEP 2020	ANGIOGRAM	Medical History	

US3112164

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:15:39

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

US3112164

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:15:39

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	28/SEP/2020 08:44
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	09/OCT/2020 13:05
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	09/OCT/2020 13:13
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	13/OCT/2020 14:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:16
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	29/OCT/2020 12:54
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	10/NOV/2020 21:50
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/JAN/2021 15:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	04/FEB/2021 12:03
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

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Data signed: (b) (4) 02 Apr 2021 21:09:07

Generated On: 09 Jun 2021 15:15:39

SAEID	USA-US062-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	
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.	False

Audit

US3112164 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112164

Form: Participant Creation

Generated On: 09 Jun 2021 15:15:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:10
User entered 'US3112164'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:25

US3112164

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:19:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:41

US3112164

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:19:06
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:26

US3112164

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:19:06
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:41

US3112164

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'SCRN'	System	10 Aug 2020 17:54:41

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:15:42
DataPoint Un-verified.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 21:12:48
User entered (b) (6) 1944' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 21:12:48
User closed query 'Please clarify. Per source DOB of (b) (6) 1944. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 21:08:08
Query 'Please clarify. Per source DOB of (b) (6) 1944. Please confirm and update as necessary.' answered with 'confirmed (b) (6) 44, endpoint DCF completed' (Site from CRA).	Matthew Musikanth (b) (4)	01 Oct 2020 21:02:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:21:49
User opened query 'Please clarify. Per source DOB of (b) (6) 1944. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:20:50
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:28

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	01 Oct 2020 21:12:48
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:21:43
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	17 Aug 2020 23:02:54
User entered '76'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'YEARS'	System	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '76'	System	01 Oct 2020 21:12:48
User entered '75'	System	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:21:47
User entered 'Male (M)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:21:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered 'I'	Karen Mylerberg (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:15:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:00
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:02:54

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered '10 Aug 2020'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Aug 2020'	System	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2020'	System	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered 'Amendment 2 (2)' reason for change:	Matthew Musikanth	10 Aug 2020 21:13:42
Data Entry Error	(b) (4)	
User entered 'Amendment 1 (1)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:50

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:22:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:26

US3112164

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:15:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'I'	System	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:15:39

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:24:55
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:15:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:32:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:15:54
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:09
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:01:19
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:00

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:56
Data point term sent to Coder	System	01 Oct 2020 21:27:37
Coding entries removed.	Matthew Musikanth (b) (4)	01 Oct 2020 21:26:54
User entered 'Hypertension' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:26:54
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:07:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:07:56
Data point term sent to Coder	System	01 Oct 2020 21:06:58
User entered 'HTN'	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'un UNK 2014'	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2014'	System	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2014'	System	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:06:51

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
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)	02 Oct 2020 05:33:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 05:33:40
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:29:17
Data point term sent to Coder	System	01 Oct 2020 21:08:03
User entered 'Hypercholesterolemia'	Matthew Musikanth	01 Oct 2020 21:07:04
	(b) (4)	

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'un UNK 2017'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:08:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 21:08:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:25
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:07:04
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2017'	System	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2017'	System	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:07:04

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
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 hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:56
Data point term sent to Coder	System	01 Oct 2020 21:27:38
Coding entries removed.	Matthew Musikanth (b) (4)	01 Oct 2020 21:27:09
User entered 'benign prostrate hyperplasia' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:27:09
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: BPH - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:08:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:08:55
Data point term sent to Coder	System	01 Oct 2020 21:08:01
User entered 'BPH'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'un UNK 2018'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2018'	System	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2018'	System	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:07:45

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:28:57
Data point term sent to Coder	System	01 Oct 2020 21:27:37
Coding entries removed.	Matthew Musikanth	01 Oct 2020 21:27:25
User entered 'Osteoarthritis' reason for change: Data Entry Error	(b) (4) (b) (4)	01 Oct 2020 21:27:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:09:48
Data point term sent to Coder	System	01 Oct 2020 21:09:04
User entered 'OA'	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'un UNK 2014'	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2014'	System	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2014'	System	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:08:06

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:10:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:10:53
Data point term sent to Coder	System	01 Oct 2020 21:10:05
User entered 'Insomnia'	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'un UNK 2019'	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:29:17
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2019'	System	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2019'	System	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	01 Oct 2020 21:10:02

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:22:54
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:57:32
Data point term sent to Coder	System	27 Oct 2020 23:56:48
User entered 'Coronary Artery Disease'	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:02
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		28 Oct 2020 18:19:14
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	28 Oct 2020 18:19:14
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	27 Oct 2020 23:56:46
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:02
User entered '1' reason for change: Data Entry Error	Matthew Musikanth	28 Oct 2020 18:19:14
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:02
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	27 Oct 2020 23:56:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:56
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	27 Oct 2020 23:56:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:02
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:02
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	28 Oct 2020 18:19:14
User entered 'Sep 2020'	System	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	28 Oct 2020 18:19:14
User entered '2020'	System	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	27 Oct 2020 23:56:46

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:22:27
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:58:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:58:33
Data point term sent to Coder	System	27 Oct 2020 23:57:48
User entered 'Hypothyroidism'	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:05
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:05
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:05
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:23:05
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2010'	System	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2010'	System	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	27 Oct 2020 23:57:32

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:37:49
Data point term sent to Coder	System	29 Oct 2020 19:37:28
User entered 'Carpal Tunnel'	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User entered 'un UNK 2014'	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User entered '0'	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:38:35
User entered '0'	Matthew Musikanth (b) (4)	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'Jan 2014'	System	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '2014'	System	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:15:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered empty.	System	29 Oct 2020 19:37:18

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered '09:20'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered '10 Aug 2020 09:20'	System	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered '67' in	Karen Mylerberg (b) (4)	17 Aug 2020 23:03:48
DataPoint set to visible.	(b) (4) System	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered '168' lb	Karen Mylerberg (b) (4)	17 Aug 2020 23:03:48
DataPoint set to visible.	(b) (4) System	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
Amendment Manager: User entered '26.36754'	System	16 Sep 2020 23:50:07
User entered '26.4'	System	17 Aug 2020 23:03:48
DataPoint set to visible.	System	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'kg/m2'	System	17 Aug 2020 23:03:48
DataPoint set to visible.	System	10 Aug 2020 17:54:54

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:11:12
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:09:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:09:47
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 14:30:29
User entered '98.1' F	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:09:47
User entered 'Oral (Oral)'	(b) (4) Karen Mylerberg (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:09:47
User entered '61'	(b) (4) Karen Mylerberg (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'bpm'	System	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:09:47
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'breaths/min'	System	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:09:47
User entered '134'	(b) (4) Karen Mylerberg (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'mmHg'	System	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:09:47
User entered '066'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User entered 'mmHg'	System	17 Aug 2020 23:03:48

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 10:42:17

US3112164

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17

US3112164

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:32:47
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:06

US3112164

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:32:47
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:19:40
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 17:36:22
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:06

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
User closed query 'Please confirm. Source indicates subject is retired. Please confirm and update as necessary.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:08:23
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:08:21
Query 'Please confirm. Source indicates subject is retired. Please confirm and update as necessary.' answered with 'Updated to reflect source correction' (Site from CRA).	Matthew Musikanth (b) (4)	01 Oct 2020 21:04:03
DataPoint Un-verified.	Matthew Musikanth (b) (4)	01 Oct 2020 21:03:59
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:03:59
User opened query 'Please confirm. Source indicates subject is retired. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:29:01
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
User entered '0'	Karen Mylerberg (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered 'I'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
User entered '0'	Karen Mylerberg (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:15:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:42:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:56:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:22
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:39

US3112164

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:32:58
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:54

US3112164

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:32:58
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:54

US3112164

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:32:58
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:04:54

US3112164

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'VISIT1'	System	17 Aug 2020 23:04:54

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:30

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:19:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:19:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 17:04:30
User entered '184856' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:30

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:30

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

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)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:21:31

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

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)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:21:31

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:21:31

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:21:31

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:21:31

US3112164

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:15:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:33:21
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:03:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:04:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:47:56

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	17 Aug 2020 23:22:41
	(b) (4)	

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '09:20'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '10 Aug 2020 09:20'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '98.1' F	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '61'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'bpm'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'breaths/min'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '134'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '066'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 03:19:17
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:22:41
User entered '11:20'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '10 Aug 2020 11:20'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '96.8' F	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '60'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'bpm'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '14'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'breaths/min'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '122'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:53
User entered '064'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	17 Aug 2020 23:22:41

US3112164

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:03
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:48

US3112164

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:03
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:22:48

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

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 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered '10 Aug 2020'	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered '10:49'	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '10 Aug 2020 10:49'	System	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:35:35
User entered 'ONCE'	System	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 17:55:11

US3112164

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:21

US3112164

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:53
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:21

US3112164

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:35:53
User entered '09:57'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:21

US3112164

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '10 Aug 2020 09:57'	System	18 Aug 2020 14:34:21

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:15:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:01
User entered '10 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:01
User entered '09:50'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '10 Aug 2020 09:50'	System	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:01
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:01
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered empty.	System	18 Aug 2020 14:34:45

US3112164

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:07
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:08

US3112164

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	17 Aug 2020 23:24:08

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:23:53', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '0c741851-50c8-46ee-b879-91d9da5be6af' User entered 'Yes (Y)'	System	10 Aug 2020 18:24:18
	System	10 Aug 2020 18:24:18

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:24:04', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '0c741851-50c8-46ee-b879-91d9da5be6af' User entered '96.8'	System	10 Aug 2020 18:24:18
	System	10 Aug 2020 18:24:18

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:24:12', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '0c741851-50c8-46ee-b879-91d9da5be6af' User entered 'No (N)'	System	10 Aug 2020 18:24:18
	System	10 Aug 2020 18:24:18

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:24:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '0c741851-50c8-46ee-b879-91d9da5be6af' User entered '10 Aug 2020 11:24'	System	10 Aug 2020 18:24:18
	System	10 Aug 2020 18:24:18

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 11:09'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 13:39'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:34:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b53a2a51-0001-41f2-b40d-dfb1dc4d4319' User entered 'Yes (Y)'	System	10 Aug 2020 21:34:48
	System	10 Aug 2020 21:34:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:34:33', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b53a2a51-0001-41f2-b40d-dfb1dc4d4319' User entered '96.8'	System	10 Aug 2020 21:34:48
	System	10 Aug 2020 21:34:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:34:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b53a2a51-0001-41f2-b40d-dfb1dc4d4319'	System	10 Aug 2020 21:34:48
User entered 'No (N)'	System	10 Aug 2020 21:34:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:34:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b53a2a51-0001-41f2-b40d-dfb1dc4d4319' User entered '10 Aug 2020 14:34'	System	10 Aug 2020 21:34:48
	System	10 Aug 2020 21:34:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 14:34'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 2'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:04', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '88dca29a-874d-4e96-a3fa-d38dc6b8687e' User entered 'Yes (Y)'	System	11 Aug 2020 19:28:27
	System	11 Aug 2020 19:28:27

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '88dca29a-874d-4e96-a3fa-d38dc6b8687e' User entered '97.4'	System	11 Aug 2020 19:28:27
	System	11 Aug 2020 19:28:27

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '88dca29a-874d-4e96-a3fa-d38dc6b8687e' User entered 'No (N)'	System	11 Aug 2020 19:28:27
	System	11 Aug 2020 19:28:27

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '88dca29a-874d-4e96-a3fa-d38dc6b8687e' User entered '11 Aug 2020 12:28'	System	11 Aug 2020 19:28:27
	System	11 Aug 2020 19:28:27

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 3'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:00:49', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f1587c97-e484-440d-bb56-0907da7b3cb3' User entered 'Yes (Y)'	System	12 Aug 2020 19:01:14
	System	12 Aug 2020 19:01:14

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f1587c97-e484-440d-bb56-0907da7b3cb3' User entered '96.8'	System	12 Aug 2020 19:01:14
	System	12 Aug 2020 19:01:14

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f1587c97-e484-440d-bb56-0907da7b3cb3'	System	12 Aug 2020 19:01:14
User entered 'No (N)'	System	12 Aug 2020 19:01:14

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:12', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f1587c97-e484-440d-bb56-0907da7b3cb3'	System	12 Aug 2020 19:01:14
User entered '12 Aug 2020 12:01'	System	12 Aug 2020 19:01:14

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 4'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:37:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b498e07e-eeaa-4de5-b6c7-4385c82b9966' User entered 'Yes (Y)'	System	14 Aug 2020 01:38:09
	System	14 Aug 2020 01:38:09

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:37:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b498e07e-eeaa-4de5-b6c7-4385c82b9966' User entered '97.8'	System	14 Aug 2020 01:38:09
	System	14 Aug 2020 01:38:09

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b498e07e-eeaa-4de5-b6c7-4385c82b9966'	System	14 Aug 2020 01:38:09
User entered 'No (N)'	System	14 Aug 2020 01:38:09

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b498e07e-eeaa-4de5-b6c7-4385c82b9966'	System	14 Aug 2020 01:38:09
User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:09

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 5'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:50:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '754e06ac-638e-44b6-a3c1-178adb340da1' User entered 'Yes (Y)'	System	14 Aug 2020 20:51:12
	System	14 Aug 2020 20:51:12

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:50:59', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '754e06ac-638e-44b6-a3c1-178adb340da1' User entered '98.0'	System	14 Aug 2020 20:51:12
	System	14 Aug 2020 20:51:12

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '754e06ac-638e-44b6-a3c1-178adb340da1'	System	14 Aug 2020 20:51:12
User entered 'No (N)'	System	14 Aug 2020 20:51:12

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '754e06ac-638e-44b6-a3c1-178adb340da1' User entered '14 Aug 2020 13:51'	System	14 Aug 2020 20:51:12
	System	14 Aug 2020 20:51:12

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 6'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:29:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4985ccb3-3fae-468c-99d1-bc60ba05d5b5' User entered 'Yes (Y)'	System	15 Aug 2020 20:30:21
	System	15 Aug 2020 20:30:21

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:13', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4985ccb3-3fae-468c-99d1-bc60ba05d5b5' User entered '97.8'	System	15 Aug 2020 20:30:21
	System	15 Aug 2020 20:30:21

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4985ccb3-3fae-468c-99d1-bc60ba05d5b5'	System	15 Aug 2020 20:30:21
User entered 'No (N)'	System	15 Aug 2020 20:30:21

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:19', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4985ccb3-3fae-468c-99d1-bc60ba05d5b5'	System	15 Aug 2020 20:30:21
User entered '15 Aug 2020 13:30'	System	15 Aug 2020 20:30:21

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 7'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f7184dbd-0272-43de-a91f-d04b510a4821' User entered 'Yes (Y)'	System	16 Aug 2020 19:00:48
	System	16 Aug 2020 19:00:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:33', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f7184dbd-0272-43de-a91f-d04b510a4821' User entered '98.2'	System	16 Aug 2020 19:00:48
	System	16 Aug 2020 19:00:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:36', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f7184dbd-0272-43de-a91f-d04b510a4821' User entered 'No (N)'	System	16 Aug 2020 19:00:48
	System	16 Aug 2020 19:00:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f7184dbd-0272-43de-a91f-d04b510a4821' User entered '16 Aug 2020 12:00'	System	16 Aug 2020 19:00:48
	System	16 Aug 2020 19:00:48

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:05', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '59b228da-badd-4c19-81d5-2c06c5e47dc0'	System	10 Aug 2020 18:25:23
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 18:25:23

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '59b228da-badd-4c19-81d5-2c06c5e47dc0' User entered 'No (N)'	System	10 Aug 2020 18:25:23
	System	10 Aug 2020 18:25:23

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:13', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '59b228da-badd-4c19-81d5-2c06c5e47dc0' User entered 'No (N)'	System	10 Aug 2020 18:25:23
	System	10 Aug 2020 18:25:23

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '59b228da-badd-4c19-81d5-2c06c5e47dc0' User entered 'None (1)'	System	10 Aug 2020 18:25:23
	System	10 Aug 2020 18:25:23

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '59b228da-badd-4c19-81d5-2c06c5e47dc0' User entered '10 Aug 2020 11:25'	System	10 Aug 2020 18:25:23
	System	10 Aug 2020 18:25:23

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 11:09'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 13:39'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:03', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '453e339d-276f-46d0-a569-327b3dab7342'	System	10 Aug 2020 21:35:22
User entered 'None (1)'	System	10 Aug 2020 21:35:22

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '453e339d-276f-46d0-a569-327b3dab7342'	System	10 Aug 2020 21:35:22
User entered 'No (N)'	System	10 Aug 2020 21:35:22

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '453e339d-276f-46d0-a569-327b3dab7342'	System	10 Aug 2020 21:35:22
User entered 'No (N)'	System	10 Aug 2020 21:35:22

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '453e339d-276f-46d0-a569-327b3dab7342'	System	10 Aug 2020 21:35:22
User entered 'None (1)'	System	10 Aug 2020 21:35:22

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '453e339d-276f-46d0-a569-327b3dab7342'	System	10 Aug 2020 21:35:22
User entered '10 Aug 2020 14:35'	System	10 Aug 2020 21:35:22

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 14:34'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 2'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fb62f6fc-b8ef-4453-860f-e0f048a0ee84'	System	11 Aug 2020 19:28:51
User entered 'None (1)'	System	11 Aug 2020 19:28:51

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:33', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fb62f6fc-b8ef-4453-860f-e0f048a0ee84'	System	11 Aug 2020 19:28:51
User entered 'No (N)'	System	11 Aug 2020 19:28:51

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fb62f6fc-b8ef-4453-860f-e0f048a0ee84'	System	11 Aug 2020 19:28:51
User entered 'No (N)'	System	11 Aug 2020 19:28:51

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:43', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fb62f6fc-b8ef-4453-860f-e0f048a0ee84'	System	11 Aug 2020 19:28:51
User entered 'None (1)'	System	11 Aug 2020 19:28:51

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fb62f6fc-b8ef-4453-860f-e0f048a0ee84'	System	11 Aug 2020 19:28:51
User entered '11 Aug 2020 12:28'	System	11 Aug 2020 19:28:51

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 3'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aebf3795-a54d-406a-81ca-79bdaad06331' User entered 'None (1)'	System	12 Aug 2020 19:01:47
	System	12 Aug 2020 19:01:47

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aebf3795-a54d-406a-81ca-79bdaad06331' User entered 'No (N)'	System	12 Aug 2020 19:01:47
	System	12 Aug 2020 19:01:47

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aebf3795-a54d-406a-81ca-79bdaad06331' User entered 'No (N)'	System	12 Aug 2020 19:01:47
	System	12 Aug 2020 19:01:47

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aebf3795-a54d-406a-81ca-79bdaad06331' User entered 'None (1)'	System	12 Aug 2020 19:01:47
	System	12 Aug 2020 19:01:47

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:01:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aebf3795-a54d-406a-81ca-79bdaad06331' User entered '12 Aug 2020 12:01'	System	12 Aug 2020 19:01:47
	System	12 Aug 2020 19:01:47

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 4'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1bb7c7ef-4d34-4ba9-bde5-8579057f533c'	System	14 Aug 2020 01:38:26
User entered 'None (1)'	System	14 Aug 2020 01:38:26

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1bb7c7ef-4d34-4ba9-bde5-8579057f533c' User entered 'No (N)'	System	14 Aug 2020 01:38:26
	System	14 Aug 2020 01:38:26

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1bb7c7ef-4d34-4ba9-bde5-8579057f533c'	System	14 Aug 2020 01:38:26
User entered 'No (N)'	System	14 Aug 2020 01:38:26

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:21', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1bb7c7ef-4d34-4ba9-bde5-8579057f533c'	System	14 Aug 2020 01:38:26
User entered 'None (1)'	System	14 Aug 2020 01:38:26

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1bb7c7ef-4d34-4ba9-bde5-8579057f533c'	System	14 Aug 2020 01:38:26
User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:26

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 5'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ce6780af-9698-42c9-8e21-45661ce0b3ad'	System	14 Aug 2020 20:51:35
User entered 'None (1)'	System	14 Aug 2020 20:51:35

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ce6780af-9698-42c9-8e21-45661ce0b3ad' User entered 'No (N)'	System	14 Aug 2020 20:51:35
	System	14 Aug 2020 20:51:35

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ce6780af-9698-42c9-8e21-45661ce0b3ad' User entered 'No (N)'	System	14 Aug 2020 20:51:35
	System	14 Aug 2020 20:51:35

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ce6780af-9698-42c9-8e21-45661ce0b3ad'	System	14 Aug 2020 20:51:35
User entered 'None (1)'	System	14 Aug 2020 20:51:35

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:33', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ce6780af-9698-42c9-8e21-45661ce0b3ad' User entered '14 Aug 2020 13:51'	System	14 Aug 2020 20:51:35
	System	14 Aug 2020 20:51:35

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 6'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '64a67b6e-e30f-4fee-996e-8186da02250b' User entered 'None (1)'	System	15 Aug 2020 20:30:39
	System	15 Aug 2020 20:30:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '64a67b6e-e30f-4fee-996e-8186da02250b' User entered 'No (N)'	System	15 Aug 2020 20:30:39
	System	15 Aug 2020 20:30:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '64a67b6e-e30f-4fee-996e-8186da02250b' User entered 'No (N)'	System	15 Aug 2020 20:30:39
	System	15 Aug 2020 20:30:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:32', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '64a67b6e-e30f-4fee-996e-8186da02250b' User entered 'None (1)'	System	15 Aug 2020 20:30:39
	System	15 Aug 2020 20:30:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:35', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '64a67b6e-e30f-4fee-996e-8186da02250b' User entered '15 Aug 2020 13:30'	System	15 Aug 2020 20:30:39
	System	15 Aug 2020 20:30:39

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 7'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:49', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e816e70b-2aff-4933-99c8-02d07ed271f1' User entered 'None (1)'	System	16 Aug 2020 19:01:06
	System	16 Aug 2020 19:01:06

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e816e70b-2aff-4933-99c8-02d07ed271f1' User entered 'No (N)'	System	16 Aug 2020 19:01:06
	System	16 Aug 2020 19:01:06

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:54', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e816e70b-2aff-4933-99c8-02d07ed271f1' User entered 'No (N)'	System	16 Aug 2020 19:01:06
	System	16 Aug 2020 19:01:06

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e816e70b-2aff-4933-99c8-02d07ed271f1'	System	16 Aug 2020 19:01:06
User entered 'None (1)'	System	16 Aug 2020 19:01:06

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:00:59', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e816e70b-2aff-4933-99c8-02d07ed271f1'	System	16 Aug 2020 19:01:06
User entered '16 Aug 2020 12:00'	System	16 Aug 2020 19:01:06

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:31', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:40', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered 'None (0)'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:49', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e'	System	10 Aug 2020 18:25:57
User entered 'No (N)'	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T11:25:54', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ff0286a-b61d-4e7f-b688-a09872a97e0e' User entered '10 Aug 2020 11:25'	System	10 Aug 2020 18:25:57
	System	10 Aug 2020 18:25:57

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 11:09'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 13:39'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:35', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:40', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:43', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:50', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:35:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered 'None (0)'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:36:03', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69'	System	10 Aug 2020 21:36:07
User entered 'No (N)'	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-10T14:36:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4cafb66-fd6d-4b16-a1a8-40df37368d69' User entered '10 Aug 2020 14:36'	System	10 Aug 2020 21:36:07
	System	10 Aug 2020 21:36:07

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Aug 2020 14:34'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 2'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:55', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:28:59', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:09', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'None (0)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered 'No (N)'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-11T12:29:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '04434d20-67a5-46c3-8434-7d684c1e7da2'	System	11 Aug 2020 19:29:27
User entered '11 Aug 2020 12:29'	System	11 Aug 2020 19:29:27

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 3'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:09', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:12', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:19', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95' User entered 'None (0)'	System	12 Aug 2020 19:02:33
	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95'	System	12 Aug 2020 19:02:33
User entered 'No (N)'	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-12T12:02:28', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a4aa1bae-54ea-45d4-85a2-3ccba449bf95'	System	12 Aug 2020 19:02:33
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 19:02:33

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 4'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:33', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:36', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:41', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:44', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'None (0)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:49', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered 'No (N)'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-13T18:38:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6c46084f-f7ea-422d-9007-71d1a2fee02c' User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:55
	System	14 Aug 2020 01:38:55

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 5'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:43', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:46', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:51', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:54', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:51:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'None (0)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:52:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered 'No (N)'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-14T13:52:05', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd2316d38-c2af-479c-9785-f17271876494' User entered '14 Aug 2020 13:52'	System	14 Aug 2020 20:52:09
	System	14 Aug 2020 20:52:09

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 6'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:53', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:30:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:31:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:31:03', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:31:05', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852' User entered 'None (0)'	System	15 Aug 2020 20:31:14
	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:31:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852'	System	15 Aug 2020 20:31:14
User entered 'No (N)'	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-15T13:31:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b25d4df0-51d0-435d-bc3b-1a5f332e9852'	System	15 Aug 2020 20:31:14
User entered '15 Aug 2020 13:31'	System	15 Aug 2020 20:31:14

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 7'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:04', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:09', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:13', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'None (0)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:19', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered 'No (N)'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-08-16T12:01:22', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc527b61-33b2-4d01-85b9-059277b6a916' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 19:01:25
	System	16 Aug 2020 19:01:25

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:55:11

US3112164

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:39:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:20

US3112164

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:39:30
User entered '17 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:20

US3112164

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:39:30
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:20

US3112164

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:39:30
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:20

US3112164

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:39:52
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	17 Aug 2020 23:24:24

US3112164

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	17 Aug 2020 23:24:24

US3112164

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	24 Aug 2020 23:07:14

US3112164

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:22
User entered '24 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	24 Aug 2020 23:07:14

US3112164

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:22
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	24 Aug 2020 23:07:14

US3112164

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:22
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	24 Aug 2020 23:07:14

US3112164

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:12
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	24 Aug 2020 23:07:20

US3112164

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	24 Aug 2020 23:07:20

US3112164

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:23
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	01 Sep 2020 00:45:30

US3112164

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:23
User entered '31 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	01 Sep 2020 00:45:30

US3112164

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:23
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	01 Sep 2020 00:45:30

US3112164

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:23
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	01 Sep 2020 00:45:30

US3112164

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:52
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	01 Sep 2020 00:45:19

US3112164

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	01 Sep 2020 00:45:19

US3112164

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:36:22

US3112164

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:22
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:36:22

US3112164

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 17:36:22

US3112164

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'VISIT2'	System	08 Sep 2020 17:36:22

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '08 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '09:27'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '08 Sep 2020 09:27'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '98.0' F	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '58'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'bpm'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'breaths/min'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '107'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:26:30
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:02:41
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:50:07
User entered '57'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '08 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '10:47'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '08 Sep 2020 10:47'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '97.9' F	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '58'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'bpm'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'breaths/min'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User entered '100'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:26:43
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:02:47
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:50:07
User entered '56'	(b) (4), (b) (6)	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	10 Sep 2020 14:43:06

US3112164

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:43:16

US3112164

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:01
User entered '8 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:43:16

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

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 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered '10:16'	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '8 Sep 2020 10:16'	System	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:45:28
User entered 'ONCE'	System	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:36:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:43:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:55
User entered '8 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:43:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:20:09
User closed query 'Please clarify. Source indicates collection time of 09:40. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:20:07
Query 'Please clarify. Source indicates collection time of 09:40. Please confirm and update as necessary.' answered with 'updated ' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 23:58:03
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 23:57:55
User entered '09:40' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 23:57:55
User opened query 'Please clarify. Source indicates collection time of 09:40. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:48:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:46:55
User entered '09:33'	(b) (4), (b) (6)	10 Sep 2020 14:43:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '8 Sep 2020 09:40'	System	08 Oct 2020 23:57:55
User entered '8 Sep 2020 09:33'	System	10 Sep 2020 14:43:35

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:15:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:48
User entered '8 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:48
User entered '09:33'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '8 Sep 2020 09:33'	System	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered empty.	System	10 Sep 2020 14:43:50

US3112164

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:48:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:36:41

US3112164

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	08 Sep 2020 17:36:41

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1cc59939-1ad7-4d4f-9903-6a7a984cff68'	System	08 Sep 2020 17:46:33
User entered 'Yes (Y)'	System	08 Sep 2020 17:46:33

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:21', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1cc59939-1ad7-4d4f-9903-6a7a984cff68' User entered '97.9'	System	08 Sep 2020 17:46:33
	System	08 Sep 2020 17:46:33

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1cc59939-1ad7-4d4f-9903-6a7a984cff68'	System	08 Sep 2020 17:46:33
User entered 'No (N)'	System	08 Sep 2020 17:46:33

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1cc59939-1ad7-4d4f-9903-6a7a984cff68' User entered '08 Sep 2020 10:46'	System	08 Sep 2020 17:46:33
	System	08 Sep 2020 17:46:33

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 10:36'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 13:06'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:47:51', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd9c5cd6b-1fe5-4850-8bc9-34873e9ab5b0'	System	09 Sep 2020 13:48:10
User entered 'Yes (Y)'	System	09 Sep 2020 13:48:10

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:47:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd9c5cd6b-1fe5-4850-8bc9-34873e9ab5b0' User entered '97.8'	System	09 Sep 2020 13:48:10
	System	09 Sep 2020 13:48:10

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd9c5cd6b-1fe5-4850-8bc9-34873e9ab5b0'	System	09 Sep 2020 13:48:10
User entered 'No (N)'	System	09 Sep 2020 13:48:10

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd9c5cd6b-1fe5-4850-8bc9-34873e9ab5b0' User entered '09 Sep 2020 06:48'	System	09 Sep 2020 13:48:10
	System	09 Sep 2020 13:48:10

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 2'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a3f55b5b-0415-4cf4-8f8f-7f1f4f8349da' User entered 'Yes (Y)'	System	09 Sep 2020 19:00:45
	System	09 Sep 2020 19:00:45

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:31', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a3f55b5b-0415-4cf4-8f8f-7f1f4f8349da' User entered '98.2'	System	09 Sep 2020 19:00:45
	System	09 Sep 2020 19:00:45

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a3f55b5b-0415-4cf4-8f8f-7f1f4f8349da'	System	09 Sep 2020 19:00:45
User entered 'No (N)'	System	09 Sep 2020 19:00:45

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:40', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a3f55b5b-0415-4cf4-8f8f-7f1f4f8349da'	System	09 Sep 2020 19:00:45
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 19:00:45

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 3'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:36:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8eb83187-449c-45bf-a749-7622b3bfa3f9' User entered 'Yes (Y)'	System	11 Sep 2020 02:37:15
	System	11 Sep 2020 02:37:15

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8eb83187-449c-45bf-a749-7622b3bfa3f9' User entered '97.6'	System	11 Sep 2020 02:37:15
	System	11 Sep 2020 02:37:15

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8eb83187-449c-45bf-a749-7622b3bfa3f9' User entered 'No (N)'	System	11 Sep 2020 02:37:15
	System	11 Sep 2020 02:37:15

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8eb83187-449c-45bf-a749-7622b3bfa3f9' User entered '10 Sep 2020 19:37'	System	11 Sep 2020 02:37:15
	System	11 Sep 2020 02:37:15

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 4'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ae3b8c6f-eeb0-4050-a23b-0d35d352e180'	System	11 Sep 2020 19:00:41
User entered 'Yes (Y)'	System	11 Sep 2020 19:00:41

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:28', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ae3b8c6f-eeb0-4050-a23b-0d35d352e180' User entered '97.2'	System	11 Sep 2020 19:00:41
	System	11 Sep 2020 19:00:41

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ae3b8c6f-eeb0-4050-a23b-0d35d352e180'	System	11 Sep 2020 19:00:41
User entered 'No (N)'	System	11 Sep 2020 19:00:41

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:38', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ae3b8c6f-eeb0-4050-a23b-0d35d352e180'	System	11 Sep 2020 19:00:41
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 19:00:41

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 5'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bb781866-b92c-4fb2-969c-43019c220e48' User entered 'Yes (Y)'	System	12 Sep 2020 19:40:19
	System	12 Sep 2020 19:40:19

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bb781866-b92c-4fb2-969c-43019c220e48' User entered '98.2'	System	12 Sep 2020 19:40:19
	System	12 Sep 2020 19:40:19

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bb781866-b92c-4fb2-969c-43019c220e48'	System	12 Sep 2020 19:40:19
User entered 'No (N)'	System	12 Sep 2020 19:40:19

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bb781866-b92c-4fb2-969c-43019c220e48' User entered '12 Sep 2020 12:40'	System	12 Sep 2020 19:40:19
	System	12 Sep 2020 19:40:19

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 6'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6f8f1b80-6840-41b1-9a48-a216038507c2'	System	13 Sep 2020 20:20:36
User entered 'Yes (Y)'	System	13 Sep 2020 20:20:36

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6f8f1b80-6840-41b1-9a48-a216038507c2' User entered '98.2'	System	13 Sep 2020 20:20:36
	System	13 Sep 2020 20:20:36

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:31', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6f8f1b80-6840-41b1-9a48-a216038507c2'	System	13 Sep 2020 20:20:36
User entered 'No (N)'	System	13 Sep 2020 20:20:36

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6f8f1b80-6840-41b1-9a48-a216038507c2'	System	13 Sep 2020 20:20:36
User entered '13 Sep 2020 13:20'	System	13 Sep 2020 20:20:36

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 7'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:13', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f609e337-d544-4e95-955c-83dca2bc8b02'	System	14 Sep 2020 19:06:29
User entered 'Yes (Y)'	System	14 Sep 2020 19:06:29

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f609e337-d544-4e95-955c-83dca2bc8b02' User entered '96.8'	System	14 Sep 2020 19:06:29
	System	14 Sep 2020 19:06:29

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f609e337-d544-4e95-955c-83dca2bc8b02'	System	14 Sep 2020 19:06:29
User entered 'No (N)'	System	14 Sep 2020 19:06:29

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f609e337-d544-4e95-955c-83dca2bc8b02'	System	14 Sep 2020 19:06:29
User entered '14 Sep 2020 12:06'	System	14 Sep 2020 19:06:29

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '43979190-abdd-47eb-b9b5-639ccbd91ad1' User entered 'None (1)'	System	08 Sep 2020 17:46:47
	System	08 Sep 2020 17:46:47

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '43979190-abdd-47eb-b9b5-639ccbd91ad1' User entered 'No (N)'	System	08 Sep 2020 17:46:47
	System	08 Sep 2020 17:46:47

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '43979190-abdd-47eb-b9b5-639ccbd91ad1' User entered 'No (N)'	System	08 Sep 2020 17:46:47
	System	08 Sep 2020 17:46:47

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '43979190-abdd-47eb-b9b5-639ccbd91ad1'	System	08 Sep 2020 17:46:47
User entered 'None (1)'	System	08 Sep 2020 17:46:47

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '43979190-abdd-47eb-b9b5-639ccbd91ad1' User entered '08 Sep 2020 10:46'	System	08 Sep 2020 17:46:47
	System	08 Sep 2020 17:46:47

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 10:36'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 13:06'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1f706f3f-689f-4488-afda-bd3e79623cb5'	System	09 Sep 2020 13:48:51
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 13:48:51

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1f706f3f-689f-4488-afda-bd3e79623cb5'	System	09 Sep 2020 13:48:51
User entered 'No (N)'	System	09 Sep 2020 13:48:51

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:32', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1f706f3f-689f-4488-afda-bd3e79623cb5'	System	09 Sep 2020 13:48:51
User entered 'No (N)'	System	09 Sep 2020 13:48:51

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1f706f3f-689f-4488-afda-bd3e79623cb5'	System	09 Sep 2020 13:48:51
User entered 'None (1)'	System	09 Sep 2020 13:48:51

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:48:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '1f706f3f-689f-4488-afda-bd3e79623cb5' User entered '09 Sep 2020 06:48'	System	09 Sep 2020 13:48:51
	System	09 Sep 2020 13:48:51

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 2'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd4511e67-ed8-4a68-b6a7-a1aa56361d32'	System	09 Sep 2020 19:01:05
User entered 'None (1)'	System	09 Sep 2020 19:01:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd4511e67-ed8-4a68-b6a7-a1aa56361d32'	System	09 Sep 2020 19:01:05
User entered 'No (N)'	System	09 Sep 2020 19:01:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:51', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd4511e67-ed8-4a68-b6a7-a1aa56361d32'	System	09 Sep 2020 19:01:05
User entered 'No (N)'	System	09 Sep 2020 19:01:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd4511e67-ed8-4a68-b6a7-a1aa56361d32'	System	09 Sep 2020 19:01:05
User entered 'None (1)'	System	09 Sep 2020 19:01:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:00:58', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd4511e67-ed8-4a68-b6a7-a1aa56361d32'	System	09 Sep 2020 19:01:05
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 19:01:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 3'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '352eb67d-d50f-4264-b4c5-3625fdef86e3' User entered 'None (1)'	System	11 Sep 2020 02:37:33
	System	11 Sep 2020 02:37:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:22', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '352eb67d-d50f-4264-b4c5-3625fdef86e3' User entered 'No (N)'	System	11 Sep 2020 02:37:33
	System	11 Sep 2020 02:37:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '352eb67d-d50f-4264-b4c5-3625fdef86e3' User entered 'No (N)'	System	11 Sep 2020 02:37:33
	System	11 Sep 2020 02:37:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '352eb67d-d50f-4264-b4c5-3625fdef86e3' User entered 'None (1)'	System	11 Sep 2020 02:37:33
	System	11 Sep 2020 02:37:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '352eb67d-d50f-4264-b4c5-3625fdef86e3' User entered '10 Sep 2020 19:37'	System	11 Sep 2020 02:37:33
	System	11 Sep 2020 02:37:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 4'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '844499d3-f61c-4433-ae34-fea563d174d1' User entered 'None (1)'	System	11 Sep 2020 19:00:59
	System	11 Sep 2020 19:00:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '844499d3-f61c-4433-ae34-fea563d174d1' User entered 'No (N)'	System	11 Sep 2020 19:00:59
	System	11 Sep 2020 19:00:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '844499d3-f61c-4433-ae34-fea563d174d1' User entered 'No (N)'	System	11 Sep 2020 19:00:59
	System	11 Sep 2020 19:00:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '844499d3-f61c-4433-ae34-fea563d174d1' User entered 'None (1)'	System	11 Sep 2020 19:00:59
	System	11 Sep 2020 19:00:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:00:55', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '844499d3-f61c-4433-ae34-fea563d174d1' User entered '11 Sep 2020 12:00'	System	11 Sep 2020 19:00:59
	System	11 Sep 2020 19:00:59

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 5'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2b0cafb0-2eb8-4bd8-80aa-fabc6dc3a858'	System	12 Sep 2020 19:40:33
User entered 'None (1)'	System	12 Sep 2020 19:40:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:21', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2b0cafb0-2eb8-4bd8-80aa-fabc6dc3a858'	System	12 Sep 2020 19:40:33
User entered 'No (N)'	System	12 Sep 2020 19:40:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2b0cafb0-2eb8-4bd8-80aa-fabc6dc3a858'	System	12 Sep 2020 19:40:33
User entered 'No (N)'	System	12 Sep 2020 19:40:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2b0cafb0-2eb8-4bd8-80aa-fabc6dc3a858'	System	12 Sep 2020 19:40:33
User entered 'None (1)'	System	12 Sep 2020 19:40:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:40:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2b0cafb0-2eb8-4bd8-80aa-fabc6dc3a858'	System	12 Sep 2020 19:40:33
User entered '12 Sep 2020 12:40'	System	12 Sep 2020 19:40:33

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 6'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7580390d-2738-44a6-b002-cb7eb7d4eaa3'	System	13 Sep 2020 20:20:55
User entered 'None (1)'	System	13 Sep 2020 20:20:55

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:43', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7580390d-2738-44a6-b002-cb7eb7d4eaa3' User entered 'No (N)'	System	13 Sep 2020 20:20:55
	System	13 Sep 2020 20:20:55

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7580390d-2738-44a6-b002-cb7eb7d4eaa3' User entered 'No (N)'	System	13 Sep 2020 20:20:55
	System	13 Sep 2020 20:20:55

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7580390d-2738-44a6-b002-cb7eb7d4eaa3'	System	13 Sep 2020 20:20:55
User entered 'None (1)'	System	13 Sep 2020 20:20:55

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7580390d-2738-44a6-b002-cb7eb7d4eaa3'	System	13 Sep 2020 20:20:55
User entered '13 Sep 2020 13:20'	System	13 Sep 2020 20:20:55

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 7'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a685325b-f7b4-44a6-bdaa-30536ef5fb4a'	System	14 Sep 2020 19:07:05
User entered 'None (1)'	System	14 Sep 2020 19:07:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:50', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a685325b-f7b4-44a6-bdaa-30536ef5fb4a' User entered 'No (N)'	System	14 Sep 2020 19:07:05
	System	14 Sep 2020 19:07:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:53', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a685325b-f7b4-44a6-bdaa-30536ef5fb4a' User entered 'No (N)'	System	14 Sep 2020 19:07:05
	System	14 Sep 2020 19:07:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:55', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a685325b-f7b4-44a6-bdaa-30536ef5fb4a' User entered 'None (1)'	System	14 Sep 2020 19:07:05
	System	14 Sep 2020 19:07:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:06:57', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'a685325b-f7b4-44a6-bdaa-30536ef5fb4a' User entered '14 Sep 2020 12:06'	System	14 Sep 2020 19:07:05
	System	14 Sep 2020 19:07:05

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:46:55', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:03', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:05', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:07', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'None (0)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered 'No (N)'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-08T10:47:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9bf4d6d8-d8a6-4706-9609-ccbe23d0d2b5' User entered '08 Sep 2020 10:47'	System	08 Sep 2020 17:47:19
	System	08 Sep 2020 17:47:19

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 10:36'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 13:06'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:21', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:27', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:31', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'None (0)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered 'No (N)'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T06:49:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'bc642663-1c2e-4ddf-93a8-60df1d31a22f' User entered '09 Sep 2020 06:49'	System	09 Sep 2020 13:49:44
	System	09 Sep 2020 13:49:44

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 2'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:12', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'None (0)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:21', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered 'No (N)'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-09T12:01:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '45f34ad2-9818-40df-9028-55cbfee6c162'	System	09 Sep 2020 19:01:28
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 19:01:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 3'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:35', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:39', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:40', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:44', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920' User entered 'None (0)'	System	11 Sep 2020 02:37:52
	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920'	System	11 Sep 2020 02:37:52
User entered 'No (N)'	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-10T19:37:50', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'aff1b3dc-c018-455a-a251-3c26deb2e920'	System	11 Sep 2020 02:37:52
User entered '10 Sep 2020 19:37'	System	11 Sep 2020 02:37:52

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 4'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:01:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931'	System	11 Sep 2020 19:02:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:01:32', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered 'None (0)'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:01:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered 'None (0)'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:01:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered 'None (0)'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:01:57', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered 'None (0)'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:02:01', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931'	System	11 Sep 2020 19:02:36
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:02:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered 'No (N)'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-11T12:02:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e20f60cd-d237-42af-ad07-bb09cf3a0931' User entered '11 Sep 2020 12:02'	System	11 Sep 2020 19:02:36
	System	11 Sep 2020 19:02:36

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 5'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753'	System	12 Sep 2020 19:41:53
User entered 'No interference with activity (1)'	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered 'None (0)'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered 'None (0)'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:24', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered 'None (0)'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:26', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered 'None (0)'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:29', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered 'None (0)'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753'	System	12 Sep 2020 19:41:53
User entered 'No (N)'	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-12T12:41:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '361d0544-f72d-4945-9a92-770cbb7bf753' User entered '12 Sep 2020 12:41'	System	12 Sep 2020 19:41:53
	System	12 Sep 2020 19:41:53

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 6'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:20:57', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'None (0)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'None (0)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986'	System	13 Sep 2020 20:21:28
User entered 'None (0)'	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'None (0)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'None (0)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'None (0)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered 'No (N)'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-13T13:21:26', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'f6238b25-1f8c-453c-8a80-6e8197711986' User entered '13 Sep 2020 13:21'	System	13 Sep 2020 20:21:28
	System	13 Sep 2020 20:21:28

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	08 Sep 2020 17:36:35
User entered 'Day 7'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:04', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'None (0)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-ee84a132'	System	14 Sep 2020 19:07:20
User entered 'No (N)'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-09-14T12:07:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'fc202f77-11b4-4e09-a9b8-eefc1e84a132'	System	14 Sep 2020 19:07:20
User entered '14 Sep 2020 12:07'	System	14 Sep 2020 19:07:20

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:35

US3112164

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:15:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:35

US3112164

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:53:50

US3112164

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:18
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:53:50

US3112164

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 17:53:50

US3112164

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:18
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:53:50

US3112164

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:53:55

US3112164

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	15 Sep 2020 17:53:55

US3112164

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:38:25
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	27 Oct 2020 23:17:03

US3112164

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:38:25
User entered '25 Sep 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 23:17:03

US3112164

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:38:25
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	27 Oct 2020 23:17:03

US3112164

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:38:25
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 23:17:03

US3112164

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:38:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	27 Oct 2020 23:17:06

US3112164

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	27 Oct 2020 23:17:06

US3112164

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:41:46
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:15:29

US3112164

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:41:46
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:15:29

US3112164

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:41:46
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:15:29

US3112164

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:41:46
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:15:29

US3112164

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:41:51
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:15:34

US3112164

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	28 Oct 2020 20:15:34

US3112164

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:46:24
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:18:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:46:24
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 22:21:13
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Natalie Moy (b) (4)	28 Oct 2020 20:18:51
answered with 'subject had adverse event (pleural effusion) as documented in AE' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Oct 2020 20:18:12
User entered '28 Oct 2020'	Natalie Moy (b) (4)	28 Oct 2020 20:18:12
	(b) (4)	

US3112164

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:46:24
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:18:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'VISIT3'	System	28 Oct 2020 20:18:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '28 Oct 2020'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '10:56'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '28 Oct 2020 10:56'	System	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '98.2' F	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '70'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'bpm'	System	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '16'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'breaths/min'	System	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '122'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:33
User entered '73'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'mmHg'	System	28 Oct 2020 20:20:12

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22

US3112164

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22

US3112164

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:48:04
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:20

US3112164

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:48:04
User entered '28 Oct 2020'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:20

US3112164

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:48
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:31

US3112164

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:48
User entered '28 Oct 2020'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:31

US3112164

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:47:48
User entered '11:20'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:31

US3112164

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered '28 Oct 2020 11:20'	System	28 Oct 2020 20:20:31

US3112164

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:48:28
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:20:35

US3112164

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	28 Oct 2020 20:20:35

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 64'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac'	System	10 Oct 2020 14:02:17
User entered 'Yes (Y)'	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac'	System	10 Oct 2020 14:02:17
User entered 'No (N)'	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac'	System	10 Oct 2020 14:02:17
User entered 'No (N)'	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:32', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac'	System	10 Oct 2020 14:02:17
User entered 'Yes (Y)'	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Please 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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:46', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac'	System	10 Oct 2020 14:02:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-10T07:01:51', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8016b2df-98c7-4610-b98a-18485e7721ac' User entered '10 Oct 2020 07:01:51'	System	10 Oct 2020 14:02:17
	System	10 Oct 2020 14:02:17

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 71'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:47:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb' User entered 'Yes (Y)'	System	17 Oct 2020 16:48:19
	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:47:42', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb'	System	17 Oct 2020 16:48:19
User entered 'No (N)'	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:47:47', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb'	System	17 Oct 2020 16:48:19
User entered 'No (N)'	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:47:52', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb'	System	17 Oct 2020 16:48:19
User entered 'Yes (Y)'	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Please 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)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:48:06', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb'	System	17 Oct 2020 16:48:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-17T09:48:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6ec2ad16-cf11-4584-a167-bc7af6f1a1bb' User entered '17 Oct 2020 09:48:11'	System	17 Oct 2020 16:48:19
	System	17 Oct 2020 16:48:19

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 78'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-25T15:48:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '202cc1db-5ae6-4135-bd12-cf89352c8b00'	System	25 Oct 2020 22:48:33
User entered 'No (N)'	System	25 Oct 2020 22:48:33

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-25T15:48:26', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '202cc1db-5ae6-4135-bd12-cf89352c8b00'	System	25 Oct 2020 22:48:33
User entered 'No (N)'	System	25 Oct 2020 22:48:33

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-10-25T15:48:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '202cc1db-5ae6-4135-bd12-cf89352c8b00' User entered '25 Oct 2020 15:48:30'	System	25 Oct 2020 22:48:33
	System	25 Oct 2020 22:48:33

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 92'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-09T12:04:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5ce826e1-7517-4d7f-86b3-cf5abffe1015' User entered 'No (N)'	System	09 Nov 2020 20:04:29
	System	09 Nov 2020 20:04:29

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-09T12:04:22', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5ce826e1-7517-4d7f-86b3-cf5abffe1015'	System	09 Nov 2020 20:04:29
User entered 'No (N)'	System	09 Nov 2020 20:04:29

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-09T12:04:26', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5ce826e1-7517-4d7f-86b3-cf5abffe1015' User entered '09 Nov 2020 12:04:26'	System	09 Nov 2020 20:04:29
	System	09 Nov 2020 20:04:29

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered 'Day 99'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-14T08:34:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e00b8ce6-cc87-4bf3-887a-af661c5e865c' User entered 'No (N)'	System	14 Nov 2020 16:34:40
	System	14 Nov 2020 16:34:40

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-14T08:34:34', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e00b8ce6-cc87-4bf3-887a-af661c5e865c' User entered 'No (N)'	System	14 Nov 2020 16:34:40
	System	14 Nov 2020 16:34:40

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-14T08:34:38', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e00b8ce6-cc87-4bf3-887a-af661c5e865c' User entered '14 Nov 2020 08:34:38'	System	14 Nov 2020 16:34:40
	System	14 Nov 2020 16:34:40

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 17:55:11

US3112164

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:25
Data entry locked.	System	10 Aug 2020 17:55:11
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 17:55:11

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-21T07:44:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3d2c4bd5-ccae-4ebe-83c6-c9387f0122e4'	System	21 Nov 2020 15:44:27
User entered 'No (N)'	System	21 Nov 2020 15:44:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-21T07:44:04', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3d2c4bd5-ccae-4ebe-83c6-c9387f0122e4'	System	21 Nov 2020 15:44:27
User entered 'No (N)'	System	21 Nov 2020 15:44:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-21T07:44:25', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3d2c4bd5-ccae-4ebe-83c6-c9387f0122e4' User entered '21 Nov 2020 07:44:25'	System	21 Nov 2020 15:44:27
	System	21 Nov 2020 15:44:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-25T07:08:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90508fb4-470d-4305-a9bc-67f4a6bcde05'	System	25 Nov 2020 15:08:19
User entered 'No (N)'	System	25 Nov 2020 15:08:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-25T07:08:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90508fb4-470d-4305-a9bc-67f4a6bcde05'	System	25 Nov 2020 15:08:19
User entered 'No (N)'	System	25 Nov 2020 15:08:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-11-25T07:08:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90508fb4-470d-4305-a9bc-67f4a6bcde05' User entered '25 Nov 2020 07:08:17'	System	25 Nov 2020 15:08:19
	System	25 Nov 2020 15:08:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-04T14:53:19', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8adb5c52-4d22-4d44-a620-a2a50b910d29' User entered 'No (N)'	System	04 Dec 2020 22:53:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-04T14:53:22', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8adb5c52-4d22-4d44-a620-a2a50b910d29'	System	04 Dec 2020 22:53:27
User entered 'No (N)'	System	04 Dec 2020 22:53:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-04T14:53:26', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8adb5c52-4d22-4d44-a620-a2a50b910d29' User entered '04 Dec 2020 14:53:26'	System	04 Dec 2020 22:53:27
	System	04 Dec 2020 22:53:27

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-09T06:59:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b7973007-013b-4099-9cc4-1f909a8971ac'	System	09 Dec 2020 14:59:18
User entered 'No (N)'	System	09 Dec 2020 14:59:18

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-09T06:59:11', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b7973007-013b-4099-9cc4-1f909a8971ac'	System	09 Dec 2020 14:59:18
User entered 'No (N)'	System	09 Dec 2020 14:59:18

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-09T06:59:16', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'b7973007-013b-4099-9cc4-1f909a8971ac' User entered '09 Dec 2020 06:59:16'	System	09 Dec 2020 14:59:18
	System	09 Dec 2020 14:59:18

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-16T07:45:38', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '49b52d3b-0a91-49fc-8516-4ae60ad2cf5d' User entered 'No (N)'	System	16 Dec 2020 15:45:48
	System	16 Dec 2020 15:45:48

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-16T07:45:41', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '49b52d3b-0a91-49fc-8516-4ae60ad2cf5d' User entered 'No (N)'	System	16 Dec 2020 15:45:48
	System	16 Dec 2020 15:45:48

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-16T07:45:45', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '49b52d3b-0a91-49fc-8516-4ae60ad2cf5d' User entered '16 Dec 2020 07:45:45'	System	16 Dec 2020 15:45:48
	System	16 Dec 2020 15:45:48

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-23T07:35:10', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd42efbd4-1e82-4815-8b6e-a194629bb797'	System	23 Dec 2020 15:35:22
User entered 'No (N)'	System	23 Dec 2020 15:35:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-23T07:35:15', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd42efbd4-1e82-4815-8b6e-a194629bb797'	System	23 Dec 2020 15:35:22
User entered 'No (N)'	System	23 Dec 2020 15:35:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-23T07:35:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd42efbd4-1e82-4815-8b6e-a194629bb797' User entered '23 Dec 2020 07:35:18'	System	23 Dec 2020 15:35:22
	System	23 Dec 2020 15:35:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-30T08:14:08', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ced7baf-d46f-47db-99dc-0ff3994bc78f' User entered 'No (N)'	System	30 Dec 2020 16:14:22
	System	30 Dec 2020 16:14:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-30T08:14:12', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ced7baf-d46f-47db-99dc-0ff3994bc78f' User entered 'No (N)'	System	30 Dec 2020 16:14:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2020-12-30T08:14:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '3ced7baf-d46f-47db-99dc-0ff3994bc78f' User entered '30 Dec 2020 08:14:18'	System	30 Dec 2020 16:14:22
	System	30 Dec 2020 16:14:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:09', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered 'Yes (Y)'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:14', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415'	System	06 Jan 2021 15:12:12
User entered 'No (N)'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:22', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered 'Yes (Y)'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '1'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '1'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:37', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '0'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:41', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415'	System	06 Jan 2021 15:12:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:46', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered 'No (N)'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-06T07:11:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7540c3a6-f301-4d55-a421-226687f42415' User entered '06 Jan 2021 07:11:56'	System	06 Jan 2021 15:12:12
	System	06 Jan 2021 15:12:12

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-13T07:35:48', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '86d5fc9f-c99c-4fab-8c6b-ac28c4f1ff3e'	System	13 Jan 2021 15:36:00
User entered 'No (N)'	System	13 Jan 2021 15:36:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-13T07:35:51', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '86d5fc9f-c99c-4fab-8c6b-ac28c4f1ff3e'	System	13 Jan 2021 15:36:00
User entered 'No (N)'	System	13 Jan 2021 15:36:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-13T07:35:56', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '86d5fc9f-c99c-4fab-8c6b-ac28c4f1ff3e' User entered '13 Jan 2021 07:35:56'	System	13 Jan 2021 15:36:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-20T12:46:02', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6106128f-64fe-49fc-aab1-b78daae98916'	System	20 Jan 2021 20:46:11
User entered 'No (N)'	System	20 Jan 2021 20:46:11

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-20T12:46:05', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6106128f-64fe-49fc-aab1-b78daae98916'	System	20 Jan 2021 20:46:11
User entered 'No (N)'	System	20 Jan 2021 20:46:11

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-20T12:46:09', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '6106128f-64fe-49fc-aab1-b78daae98916'	System	20 Jan 2021 20:46:11
User entered '20 Jan 2021 12:46:09'	System	20 Jan 2021 20:46:11

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-30T17:59:18', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ccfa1ab3-1909-4469-880b-789a02a4311a' User entered 'No (N)'	System	31 Jan 2021 01:59:28
	System	31 Jan 2021 01:59:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-30T17:59:20', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ccfa1ab3-1909-4469-880b-789a02a4311a' User entered 'No (N)'	System	31 Jan 2021 01:59:28
	System	31 Jan 2021 01:59:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-01-30T17:59:23', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'ccfa1ab3-1909-4469-880b-789a02a4311a' User entered '30 Jan 2021 17:59:23'	System	31 Jan 2021 01:59:28
	System	31 Jan 2021 01:59:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-03T07:33:13', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9a41e48d-3ff3-4fe8-ba4c-42fd1c5e17a1' User entered 'No (N)'	System	03 Feb 2021 15:33:30
	System	03 Feb 2021 15:33:30

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-03T07:33:17', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9a41e48d-3ff3-4fe8-ba4c-42fd1c5e17a1' User entered 'No (N)'	System	03 Feb 2021 15:33:30
	System	03 Feb 2021 15:33:30

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-03T07:33:28', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9a41e48d-3ff3-4fe8-ba4c-42fd1c5e17a1' User entered '03 Feb 2021 07:33:28'	System	03 Feb 2021 15:33:30
	System	03 Feb 2021 15:33:30

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-12T12:21:36', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7150dd54-071a-40dd-a9ce-8ae4cb20760e' User entered 'No (N)'	System	12 Feb 2021 22:49:00
	System	12 Feb 2021 22:49:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-12T12:21:38', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7150dd54-071a-40dd-a9ce-8ae4cb20760e' User entered 'No (N)'	System	12 Feb 2021 22:49:00
	System	12 Feb 2021 22:49:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-12T12:21:41', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '7150dd54-071a-40dd-a9ce-8ae4cb20760e' User entered '12 Feb 2021 12:21:41'	System	12 Feb 2021 22:49:00
	System	12 Feb 2021 22:49:00

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-17T09:16:30', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd25f9e54-ca5f-482e-9c3d-57c5b7693d8b' User entered 'No (N)'	System	17 Feb 2021 17:20:45
	System	17 Feb 2021 17:20:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-17T09:16:31', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd25f9e54-ca5f-482e-9c3d-57c5b7693d8b' User entered 'No (N)'	System	17 Feb 2021 17:20:45
	System	17 Feb 2021 17:20:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-17T09:16:35', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'd25f9e54-ca5f-482e-9c3d-57c5b7693d8b' User entered '17 Feb 2021 09:16:35'	System	17 Feb 2021 17:20:45
	System	17 Feb 2021 17:20:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-26T09:34:07-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9cbe2821-5717-4675-bce9-83f01599318c' User entered 'No (N)'	System	02 Mar 2021 19:39:44
	System	02 Mar 2021 19:39:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-26T09:34:09-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9cbe2821-5717-4675-bce9-83f01599318c'	System	02 Mar 2021 19:39:44
User entered 'No (N)'	System	02 Mar 2021 19:39:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-02-26T09:34:13-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9cbe2821-5717-4675-bce9-83f01599318c' User entered '26 Feb 2021 17:34:13'	System	02 Mar 2021 19:39:44
	System	02 Mar 2021 19:39:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-05T12:53:21-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2ff3523c-0267-4dfb-8368-48bef34f1579'	System	05 Mar 2021 20:53:31
User entered 'No (N)'	System	05 Mar 2021 20:53:31

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-05T12:53:24-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2ff3523c-0267-4dfb-8368-48bef34f1579'	System	05 Mar 2021 20:53:31
User entered 'No (N)'	System	05 Mar 2021 20:53:31

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-05T12:53:27-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '2ff3523c-0267-4dfb-8368-48bef34f1579'	System	05 Mar 2021 20:53:31
User entered '05 Mar 2021 20:53:27'	System	05 Mar 2021 20:53:31

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-10T07:01:58-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '25e5629a-308b-4758-835b-c20abe00524e'	System	10 Mar 2021 15:02:19
User entered 'No (N)'	System	10 Mar 2021 15:02:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-10T07:02:09-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '25e5629a-308b-4758-835b-c20abe00524e'	System	10 Mar 2021 15:02:19
User entered 'No (N)'	System	10 Mar 2021 15:02:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-10T07:02:12-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '25e5629a-308b-4758-835b-c20abe00524e' User entered '10 Mar 2021 07:02:12'	System	10 Mar 2021 15:02:19
	System	10 Mar 2021 15:02:19

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-17T09:00:26-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '94c67fa8-0a54-422b-ba0b-196170ceb60e'	System	17 Mar 2021 16:00:54
User entered 'No (N)'	System	17 Mar 2021 16:00:54

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-17T09:00:28-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '94c67fa8-0a54-422b-ba0b-196170ceb60e'	System	17 Mar 2021 16:00:54
User entered 'No (N)'	System	17 Mar 2021 16:00:54

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-17T09:00:31-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '94c67fa8-0a54-422b-ba0b-196170ceb60e' User entered '17 Mar 2021 09:00:31'	System	17 Mar 2021 16:00:54
	System	17 Mar 2021 16:00:54

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-24T08:16:29-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5488c715-140c-4e9d-b493-366cd6fb9f68'	System	24 Mar 2021 15:16:40
User entered 'No (N)'	System	24 Mar 2021 15:16:40

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-24T08:16:31-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5488c715-140c-4e9d-b493-366cd6fb9f68'	System	24 Mar 2021 15:16:40
User entered 'No (N)'	System	24 Mar 2021 15:16:40

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-24T08:16:35-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '5488c715-140c-4e9d-b493-366cd6fb9f68'	System	24 Mar 2021 15:16:40
User entered '24 Mar 2021 08:16:35'	System	24 Mar 2021 15:16:40

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-31T07:43:12-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '309e9e81-8142-4c53-b6d3-3b673b8bb71d'	System	07 Apr 2021 15:25:28
User entered 'No (N)'	System	07 Apr 2021 15:25:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-31T07:43:15-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '309e9e81-8142-4c53-b6d3-3b673b8bb71d'	System	07 Apr 2021 15:25:28
User entered 'No (N)'	System	07 Apr 2021 15:25:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-31T07:43:18-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '309e9e81-8142-4c53-b6d3-3b673b8bb71d'	System	07 Apr 2021 15:25:28
User entered '31 Mar 2021 07:43:18'	System	07 Apr 2021 15:25:28

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-07T08:25:26-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4adccf21-0ba3-427d-ba30-0760a893175d' User entered 'No (N)'	System	07 Apr 2021 15:25:35
	System	07 Apr 2021 15:25:35

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-07T08:25:28-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4adccf21-0ba3-427d-ba30-0760a893175d' User entered 'No (N)'	System	07 Apr 2021 15:25:35

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-07T08:25:31-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '4adccf21-0ba3-427d-ba30-0760a893175d' User entered '07 Apr 2021 08:25:31'	System	07 Apr 2021 15:25:35
	System	07 Apr 2021 15:25:35

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-14T07:06:36-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90936c5e-ddff-44b3-82b9-9ca03e416208'	System	14 Apr 2021 14:06:45
User entered 'No (N)'	System	14 Apr 2021 14:06:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-14T07:06:39-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90936c5e-ddff-44b3-82b9-9ca03e416208'	System	14 Apr 2021 14:06:45
User entered 'No (N)'	System	14 Apr 2021 14:06:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-14T07:06:41-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '90936c5e-ddff-44b3-82b9-9ca03e416208'	System	14 Apr 2021 14:06:45
User entered '14 Apr 2021 07:06:41'	System	14 Apr 2021 14:06:45

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-21T07:25:10-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9c5aee76-f069-45aa-90e9-76f059f946ad' User entered 'No (N)'	System	21 Apr 2021 14:25:22
	System	21 Apr 2021 14:25:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-21T07:25:14-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9c5aee76-f069-45aa-90e9-76f059f946ad'	System	21 Apr 2021 14:25:22
User entered 'No (N)'	System	21 Apr 2021 14:25:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-21T07:25:17-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '9c5aee76-f069-45aa-90e9-76f059f946ad'	System	21 Apr 2021 14:25:22
User entered '21 Apr 2021 07:25:17'	System	21 Apr 2021 14:25:22

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-28T06:48:46-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8099643d-87fe-447f-8c78-00b50140584d' User entered 'No (N)'	System	29 Apr 2021 01:09:44
	System	29 Apr 2021 01:09:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-28T06:48:48-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8099643d-87fe-447f-8c78-00b50140584d' User entered 'No (N)'	System	29 Apr 2021 01:09:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-04-28T06:48:53-07:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: '8099643d-87fe-447f-8c78-00b50140584d' User entered '28 Apr 2021 06:48:53'	System	29 Apr 2021 01:09:44
	System	29 Apr 2021 01:09:44

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:16:41

US3112164

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:15:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:41
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:16:41

US3112164

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:15:39

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)	29 Apr 2021 19:48:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-02T11:39:51-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e0bfaa34-57f8-4006-9501-e758e58b0f61'	System	05 Mar 2021 20:53:26
User entered 'No (N)'	System	05 Mar 2021 20:53:26

US3112164

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:15:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:48:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F77BC7F-2909-4F9E-803E-C144186718C2)', Time: '2021-03-02T11:40:00-08:00', User OID: 'PatientReportedOutcome (US3112164)', ODM File OID: 'e0bfaa34-57f8-4006-9501-e758e58b0f61'	System	05 Mar 2021 20:53:26
User entered '02 Mar 2021 19:40:00'	System	05 Mar 2021 20:53:26

US3112164

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:47:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:49:48
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:12:42

US3112164

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:47:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:49:48
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:12:42

US3112164

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:47:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:49:48
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:12:42

US3112164

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:47:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:49:48
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:12:42

US3112164

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:47:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:49:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:12:48

US3112164

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:53:22
User entered 'I'	System	07 Dec 2020 21:12:48

US3112164

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:51:27
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:13:00

US3112164

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:51:27
User entered '7 Dec 2020'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:13:00

US3112164

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:51:27
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:13:00

US3112164

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:51:27
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:13:00

US3112164

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:52:54
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	07 Dec 2020 21:13:07

US3112164

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User entered 'I'	System	07 Dec 2020 21:13:07

US3112164

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Jan 2021 17:35:44

US3112164

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:05
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 17:36:01
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	06 Jan 2021 17:36:01
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	06 Jan 2021 17:36:01
User entered '05 Jan 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Jan 2021 17:36:01
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 17:35:44
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	06 Jan 2021 17:35:44
User entered '05 Jan 2020'	Matthew Musikanth (b) (4)	06 Jan 2021 17:35:44

US3112164

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:05
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	06 Jan 2021 17:35:44

US3112164

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:05
User entered empty.	Matthew Musikanth (b) (4)	06 Jan 2021 17:35:44

US3112164

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:28
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Jan 2021 17:36:07

US3112164

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User entered 'I'	System	06 Jan 2021 17:36:07

US3112164

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:37:30
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:39:14

US3112164

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:37:30
User entered '5 Feb 2021'	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:39:14

US3112164

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:37:30
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:39:14

US3112164

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:37:30
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:39:14

US3112164

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:37:35
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:39:19

US3112164

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:11
User entered 'I'	System	05 Feb 2021 19:39:19

US3112164

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:48:49
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:51

US3112164

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:48:49
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:51

US3112164

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

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 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:48:49
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:51

US3112164

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'VISIT4'	System	08 Mar 2021 22:29:51

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered '9:00'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered '8 Mar 2021 9:00'	System	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	30 Mar 2021 16:22:46
	(b) (4)	

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
User entered '60'	Brenda Grande (b) (4)	30 Mar 2021 16:22:46
	(b) (4)	

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'bpm'	System	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
User entered '16'	Brenda Grande (b) (4)	30 Mar 2021 16:22:46
	(b) (4)	

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'breaths/min'	System	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered '128'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'mmHg'	System	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:01:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User entered '66'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'mmHg'	System	30 Mar 2021 16:22:46

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08

US3112164

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08

US3112164

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:48:53
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:31
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:59

US3112164

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:48:53
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:31
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:59

US3112164

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:53:03
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:43

US3112164

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:53:03
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:43

US3112164

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:53:03
User entered '09:20'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:43

US3112164

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered '8 Mar 2021 09:20'	System	08 Mar 2021 22:30:43

US3112164

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:49:29
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:30:52

US3112164

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:08
User entered 'I'	System	08 Mar 2021 22:30:52

US3112164

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 16:39:35

US3112164

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
User entered '6 Apr 2021'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 16:39:35

US3112164

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 16:39:35

US3112164

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 16:39:35

US3112164

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 16:39:28

US3112164

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 16:39:28

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:27:14
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:52:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:27:14
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:52:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:27:14
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:52:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 20:52:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:05:29

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:05:29

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:50:48
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:50:48
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:29:13
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '1'	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:15:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'I'	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered empty.	System	05 Jan 2021 20:55:51
DataPoint set to visible.	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered empty.	System	05 Jan 2021 20:55:51
DataPoint set to visible.	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '09:42'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '5 Jan 2021 09:42'	System	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '98.3' F	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '58'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'bpm'	System	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '16'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'breaths/min'	System	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '166'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '83'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:55:51

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:15:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered empty.	System	05 Jan 2021 20:55:51
DataPoint set to visible.	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '10:50'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '5 Jan 2021 10:50'	System	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '98.3' F	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '60'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'bpm'	System	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '16'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'breaths/min'	System	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '152'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:27
User entered '78'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	05 Jan 2021 20:56:55

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:38
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:13

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:38
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:13

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

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)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mRNA-1273'	System	05 Jan 2021 20:57:36
DataPoint set to visible.	System	05 Jan 2021 20:54:21

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered '10:19'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '5 Jan 2021 10:19'	System	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:51
User entered 'ONCE'	System	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 20:57:36

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:59
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:13:18

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:59
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:13:18

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:30:59
User entered '10:00'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:13:18

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '5 Jan 2021 10:00'	System	05 Jan 2021 22:13:18

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:31:04
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:14:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:31:04
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:14:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:15:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:31:04
User entered '09:54'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:14:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:15:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '5 Jan 2021 09:54'	System	05 Jan 2021 22:14:12

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:14:18

US3112164

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'I'	System	05 Jan 2021 22:14:18

US3112164

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:25
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Jan 2021 00:33:56

US3112164

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:25
User entered '12 Jan 2021'	Natalie Moy (b) (4) (b) (4)	13 Jan 2021 00:33:56

US3112164

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:25
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	13 Jan 2021 00:33:56

US3112164

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:25
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Jan 2021 00:33:56

US3112164

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:33:31
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Jan 2021 00:34:01

US3112164

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'I'	System	13 Jan 2021 00:34:01

US3112164

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '1'	System	13 Jan 2021 00:34:01
DataPoint set to visible.	System	13 Jan 2021 00:34:01

US3112164

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:34:56
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:14:50

US3112164

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:34:56
User entered '2 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:14:50

US3112164

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:34:56
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:14:50

US3112164

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'OLD29'	System	09 Feb 2021 20:14:50

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '2 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '09:31'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '2 Feb 2021 09:31'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '97.6' F	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '69'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'bpm'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '16'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'breaths/min'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '141'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '68'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '2 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '10:24'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '2 Feb 2021 10:24'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '98.1' F	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '64'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'bpm'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '16'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'breaths/min'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '144'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:39
User entered '72'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	09 Feb 2021 21:14:23

US3112164

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:47
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:30

US3112164

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:35:47
User entered '2 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:30

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

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)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mRNA-1273'	System	09 Feb 2021 21:14:55
DataPoint set to visible.	System	13 Jan 2021 00:34:01

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered '2 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered '09:53'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '2 Feb 2021 09:53'	System	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:14
User entered 'ONCE'	System	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:15:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 21:14:55

US3112164

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:36:18
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:02

US3112164

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'I'	System	09 Feb 2021 21:15:02

US3112164

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:41:00
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:16

US3112164

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:41:00
User entered '9 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:16

US3112164

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:41:00
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:16

US3112164

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:15:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:41:00
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:16

US3112164

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:41:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 21:15:22

US3112164

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:15:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'I'	System	09 Feb 2021 21:15:22

US3112164

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:43:51
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:05

US3112164

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:43:51
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:05

US3112164

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:43:51
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:05

US3112164

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:15:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'OLD57'	System	08 Mar 2021 22:28:05

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '9:00'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '8 Mar 2021 9:00'	System	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '60'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'bpm'	System	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '16'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'breaths/min'	System	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '128'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:23
User entered '66'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered 'mmHg'	System	08 Mar 2021 22:28:36

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46

US3112164

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:15:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46

US3112164

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:29
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:15

US3112164

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:15:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:44:29
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:15

US3112164

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:45:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:28

US3112164

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:45:15
User entered '8 Mar 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:28

US3112164

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:45:15
User entered '09:20'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 22:29:28

US3112164

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:15:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:46
User entered '8 Mar 2021 09:20'	System	08 Mar 2021 22:29:28

US3112164

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:15:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:39:00
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:10:25

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:43:39
User entered 'USA-US062-2020-mRNA-1273-P301000002'	System	28 Sep 2020 12:43:07
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 12:43:07

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:30:32
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'due to acute coronary event ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:57:06
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:33:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:15:11
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:36:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:36:24
Data point term sent to Coder	System	12 Oct 2020 19:54:11
Coding entries removed.	Matthew Musikanth (b) (4)	12 Oct 2020 19:54:08
User entered 'Severe Coronary Artery Disease' reason for change: New Information	Matthew Musikanth (b) (4)	12 Oct 2020 19:54:08

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The subject had a CABG while in trial as a response to SOB and chest tightness he had prior to his entry in the trial. Please clarify if there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reason for the surgery would be considered a SAE.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:03:24
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:03:17
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:08:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:08:13
Data point term sent to Coder	System	08 Oct 2020 20:48:31
Query 'PV Query: The subject had a CABG while in trial as a response to SOB and chest tightness he had prior to his entry in the trial. Please clarify if there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reason for the surgery would be considered a SAE.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:48:05
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:58
DataPoint Un-verified.	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:51
Coding entries removed.	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:51
User entered 'Acute Coronary Event' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:51

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The subject had a CABG while in trial as a response to SOB and chest tightness he had prior to his entry in the trial. Please clarify if there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reason for the surgery would be considered a SAE.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 17:02:27
Query 'PV Query: This 76 yo male had a CABG which was performed while in trial as a response to SOB and chest tightness he had prior to his entry in the trial; he has history of hypertension, hypercholesterolemia. Please clarify whether there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reasons for the surgery.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 17:02:16
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:33:41
User opened query 'PV Query: This 76 yo male had a CABG which was performed while in trial as a response to SOB and chest tightness he had prior to his entry in the trial; he has history of hypertension, hypercholesterolemia. Please clarify whether there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reasons for the surgery.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:33:10
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:15:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:15:47
Data point term sent to Coder	System	25 Sep 2020 21:14:52
User entered 'Coronary Artery Bypass Graft x3'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

1854 of 2595

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 22:11:22
User closed query 'PV Query: Please review the event start date and update if appropriate for the serious event Coronary artery disease considering that the reported start date is 18Sep2020, while the hospital discharge summary indicates admission date of 16Sep2020.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 20:34:57
Query 'PV Query: Please review the event start date and update if appropriate for the serious event Coronary artery disease considering that the reported start date is 18Sep2020, while the hospital discharge summary indicates admission date of 16Sep2020.' answered with 'has been updated ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:56:14
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:11
User entered '16 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:11
User opened query 'PV Query: Please review the event start date and update if appropriate for the serious event Coronary artery disease considering that the reported start date is 18Sep2020, while the hospital discharge summary indicates admission date of 16Sep2020.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:41:32
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:15:06
User closed query 'PV Query: End date for the event was the same as start date however the subject was discharged on 24 Sep 2020. Please consider updating the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:03:38
Query 'PV Query: End date for the event was the same as start date however the subject was discharged on 24 Sep 2020. Please consider updating the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved).' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:48:11
DataPoint Un-verified.	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:51
User entered '24 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	08 Oct 2020 20:47:51
User opened query 'PV Query: End date for the event was the same as start date however the subject was discharged on 24 Sep 2020. Please consider updating the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved).' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:32:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
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	25 Sep 2020 21:23:11
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	25 Sep 2020 21:23:11
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	25 Sep 2020 21:22:26

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '0'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'I'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:22:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Sep 2020 21:15:44
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 by data change (Site from System).		25 Sep 2020 21:15:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Sep 2020 21:14:49
User entered 'I'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '24 Sep 2020'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Sep 2020 21:15:44
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '0'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '0'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'I'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:14:40
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:03:55
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:32:39
DataPoint Un-verified.	Matthew Musikanth (b) (4)	08 Oct 2020 20:32:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	08 Oct 2020 20:32:29
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:34:03
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'None (NONE)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '0'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:18:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 22:06:27
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 00:40:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered '1'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'I'	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:22:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Sep 2020 21:23:11
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 21:22:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 21:22:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Sep 2020 21:22:26
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 21:14:49
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 22:11:37
User closed query 'PV Query: Please clarify details of COVID-19 testing considering that blood culture is not typical test.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 20:35:20
User closed query 'PV Query: The hospital discharge summary for admission starting 16Sep2020 includes additional diagnoses that are not listed as SAEs. Please consider whether acute tubular necrosis, partial small-bowel obstruction, postoperative atrial fibrillation with controlled ventricular rate, and postoperative pericarditis meet criteria for reporting as SAEs and update SAE form if appropriate.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 20:35:06
Query 'PV Query: Please clarify details of COVID-19 testing considering that blood culture is not typical test.' answered with 'negative ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:32
Query 'PV Query: The hospital discharge summary for admission starting 16Sep2020 includes additional diagnoses that are not listed as SAEs. Please consider whether acute tubular necrosis, partial small-bowel obstruction, postoperative atrial fibrillation with controlled ventricular rate, and postoperative pericarditis meet criteria for reporting as SAEs and update SAE form if appropriate.' answered with 'does not meet criteria for SAE' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:20
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:11

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT. STATES HE HAD GONE IN FOR ELECTIVE CARIAC CATH TO EVAL EXERTIONAL SX'S (SOB, CHEST TIGHTNESS). PT. STATES HAS HAD SX'S FOR ATLEAST 6 MONTHS. STATES DID NOT SHARE THIS WITH SITE STAFF AS HE DID NO THINK MUCH OF IT. STATES WENT I AND ON ANGIO HAD SIG DISEASE OF LEFT MAIN AND LAD. AT THAT TIME CABG X3 PERFORMED. WAS HOSPITALIZED AT SHARP MEMORIAL FROM 16 SEP 2020 - 24 SEP 2020. NOW AT HOME DOING MUCH BETTER.' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	11 Jan 2021 16:55:11
User opened query 'PV Query: Please clarify details of COVID-19 testing considering that blood culture is not typical test.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:42:20
User opened query 'PV Query: The hospital discharge summary for admission starting 16Sep2020 includes additional diagnoses that are not listed as SAEs. Please consider whether acute tubular necrosis, partial small-bowel obstruction, postoperative atrial fibrillation with controlled ventricular rate, and postoperative pericarditis meet criteria for reporting as SAEs and update SAE form if appropriate.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:42:06
User closed query 'Per DM CLR: SAE Narrative = CARIDC CATH, PT. STATES HAS HAD SX'S FOR ATLEAST 6 MONTHS and STATES WENT I AND ON ANGIO HAD SIG DISEASE OF LEFT MAIN AND LAD. However, these information were not recorded in the appropriate eCRF pages (Med History and ConProc eCRFs). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:37:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:14:35

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = CARIDC CATH, PT. STATES HAS HAD SX'S FOR ATLEAST 6 MONTHS and STATES WENT I AND ON ANGIO HAD SIG DISEASE OF LEFT MAIN AND LAD. However, these information were not recorded in the appropriate eCRF pages (Med History and ConProc eCRFs). Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 23:12:48
	Natalie Moy (b) (4)	19 Oct 2020 23:12:18
User entered 'PT. STATES HE HAD GONE IN FOR ELECTIVE CARIaC CATH TO EVAL EXERTIONAL SX'S (SOB, CHEST TIGHTNESS). PT. STATES HAS HAD SX'S FOR ATLEAST 6 MONTHS. STATES DID NOT SHARE THIS WITH SITE STAFF AS HE DID NO THINK MUCH OF IT. STATES WENT I AND ON ANGIO HAD SIG DISEASE OF LEFT MAIN AND LAD. AT THAT TIME CABG X3 PERFORMED. WAS HOSPITALIZED AT SHARP MEMORIAL FROM 18 SEP 2020 - 24 SEP 2020. NOW AT HOME DOING MUCH BETTER.' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 23:12:18
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 14:29:28
User opened query 'Per DM CLR: SAE Narrative = CARIDC CATH, PT. STATES HAS HAD SX'S FOR ATLEAST 6 MONTHS and STATES WENT I AND ON ANGIO HAD SIG DISEASE OF LEFT MAIN AND LAD. However, these information were not recorded in the appropriate eCRF pages (Med History and ConProc eCRFs). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 00:41:22

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary submitted, 12Oct2020' (Site from Safety).	Matthew Musikanth (b) (4)	12 Oct 2020 19:53:22
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:04:55
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:04:49
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:04:46
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:04:35
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 'Pending Medical Records' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:49:26
Query 'PV Query: Please provide any additional 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).' answered with 'Pending Medical Records' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:49:22

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending Medical Records' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:49:18
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	08 Oct 2020 20:49:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:34:20
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:34:13
Query 'PV Query: This 76 yo male had a CABG which was performed while in trial as a response to SOB and chest tightness he had prior to his entry in the trial; he has history of hypertension, hypercholesterolemia. Please clarify whether there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reasons for the surgery.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:33:04
User opened query 'PV Query: This 76 yo male had a CABG which was performed while in trial as a response to SOB and chest tightness he had prior to his entry in the trial; he has history of hypertension, hypercholesterolemia. Please clarify whether there was an aggravation of his symptoms or results of investigations to justify a new/emergent SAE in the trial. Surgery in itself would not be a SAE, only the reasons for the surgery.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:32:39
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:32:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

1890 of 2595

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:31:38
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 17:31:21
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:41:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Sep 2020 21:22:26
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Sep 2020 21:22:26
User entered 'Pt. states he had gone in for elective caridc cath to eval exertional sx's (SOB, chest tightness). Pt. states has had sx's for atleast 6 months. States did not share this with site staff as he did no think much of it. States went i and on angio had sig disease of left main and LAD. At that time CABG x3 performed. Was hospitalized at sharp memorial from 18 Sep 2020 - 24 Sep 2020. Now at home doing much better.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Sep 2020 21:22:26
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Sep 2020 21:14:49
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 21:14:49

US3112164

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:15:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 21:15:44

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:12:56
User entered 'USA-US062-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	09 Oct 2020 13:12:52

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:04:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:04:51
Data point term sent to Coder	System	08 Oct 2020 20:15:09
User entered 'Pleural Effusion'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:31
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:38
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:22:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 20:15:34
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:34
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 20:15:02
User entered '06:00'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 20:15:34
User entered '02 Oct 2020 06:00'	System	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:55:55
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:02
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:02
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:52
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:55:56
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	28 Oct 2020 20:21:27
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	28 Oct 2020 20:21:27
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	28 Oct 2020 20:21:02
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:02
User entered '2 Oct 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:02
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:55
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:57
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:23:58
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:00
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:02
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:05
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:03
User entered 'I'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:06
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:08
User entered '04 Oct 2020'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:22:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:11
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Oct 2020 20:15:34
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		08 Oct 2020 20:15:34
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:34
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Oct 2020 20:15:02
User entered 'Unknown (UNK)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:12
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:14
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:18
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:16
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:20
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:21
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:22:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:59:40
User closed query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken for the event, pleural effusion, with study drug from none to not applicable. please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 16:22:44
Query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken for the event, pleural effusion, with study drug from none to not applicable. please update the EDC accordingly.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	15 Feb 2021 16:26:29
DataPoint Un-verified.	Matthew Musikanth (b) (4)	15 Feb 2021 16:25:09
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Feb 2021 16:25:09
User opened query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken for the event, pleural effusion, with study drug from none to not applicable. please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 04:02:11
User closed query 'Per source - action taken with IP is 'NONE'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 21:27:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 21:27:16
Query 'Per source - action taken with IP is 'NONE'. Please reconcile. ' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4)	03 Feb 2021 16:11:02
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Grande (b) (4)	03 Feb 2021 16:10:52
User opened query 'Per source - action taken with IP is 'NONE'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 22:03:21
User closed query '(SAE 2) PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:21:18

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

Action taken with investigational product

Audit	User	Time (GMT)
Query '(SAE 2) PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4)	09 Nov 2020 18:53:20
DataPoint Un-verified.	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Natalie Moy (b) (4)	09 Nov 2020 18:53:09
reason for change: Data Entry Error	(b) (4)	
User opened query '(SAE 2) PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:37:33
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:23
User entered 'None (NONE)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:24
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:35
User entered 'I'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:36
User entered 'I'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:56:08
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:21:27
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:39
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:22:49
User closed query 'PV Query: Please send a hospital discharge summary for both hospitalizations with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:21:32
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:21:21
Query 'PV Query: Please send a hospital discharge summary for both hospitalizations with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent ' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 22:12:38
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 'yes, blood culture on 2oct2020, tested negative for covid-19' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 20:37:47
User opened query 'PV Query: Please send a hospital discharge summary for both hospitalizations with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:37:52
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:37:44
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:24:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

1928 of 2595

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient presented at hospital for potential complications with prior CABG x3, diagnosis of Left plueral effusion. Chest tube placed and drained on 02Oct2020, monitored until discharge on 04oct2020. Prescription of Levaquin as additional treatment / prophylaxis.'	Matthew Musikanth (b) (4)	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 20:15:02

US3112164

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:15:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 20:15:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:15:39

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per ETRTR: Please confirm medication dosed for indication SAE "Coronary Artery Bypass Graft", thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:00:17
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:43:24
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	21 Oct 2020 17:45:08
Query 'Per ETRTR: Please confirm medication dosed for indication SAE "Coronary Artery Bypass Graft", thanks.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	21 Oct 2020 17:45:02
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:24:35
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:43:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:15:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please confirm medication dosed for indication SAE "Coronary Artery Bypass Graft", thanks.' (Site from CRA). User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	29 Sep 2020 17:22:26
	Karen Mylerberg (b) (4) [REDACTED]	18 Aug 2020 14:35:20

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:47:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:38:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:38:21
Data point term sent to Coder	System	18 Aug 2020 14:37:05
User entered 'Amlodipine'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:29:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:50
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:46:09
User entered 'Hypertension'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '10'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:36:09
User entered 'UN UNK 2018'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 14:36:09

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:47:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:00:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:00:22
Data point term sent to Coder	System	18 Aug 2020 14:37:08
User entered 'Atenolol XS'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:30:10
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:10:54
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:46:19
User entered 'Hypertension'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '50'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:37:02
User entered 'UN UNK 2014'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:08
DataPoint Un-verified.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:43
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:21:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:10
Query 'Please provide source.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	27 Oct 2020 22:41:27
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:36:32
DataPoint Un-verified.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:43
User entered '17 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User entered '1'	System	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User entered '1'	System	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:38
User entered '804 (804)'	System	18 Aug 2020 14:37:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:47:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: NORFLOXACIN, PRODUCTSYNONYM: NOROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:25:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:25:28
Data point term sent to Coder	System	18 Aug 2020 14:38:11
User entered 'Noroxin'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Oct 2020 10:31:15
	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:11:03
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:46:35
User entered 'Benign prostatic hyperplasia'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:21:47
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'As reported by patient. ' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:11:30
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:46:45
User entered '100'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:38:02
User entered 'UN UNK 2018'	Karen Mylerberg (b) (4)	18 Aug 2020 14:38:02
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 14:38:02

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:47:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:40:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:40:32
Data point term sent to Coder	System	18 Aug 2020 14:39:15
User entered 'Crestor'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:31:38
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:11:34
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:47:06
User entered 'Hypercholesterolemia'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '40'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:39:14
User entered 'UN UNK 2017'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 14:39:14

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:23:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:23:21
Data point term sent to Coder	System	18 Aug 2020 14:40:19
User entered 'Tramadol'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:31:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:11:40
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:47:19
User entered 'Osteoarthritis pain relief'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '15'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'as needed (PRN)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:40:04
User entered 'UN UNK 2014'	Karen Mylerberg (b) (4)	18 Aug 2020 14:40:04
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:42:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:42:25
Data point term sent to Coder	System	18 Aug 2020 14:41:23
User entered 'Ambien'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:32:17
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:11:45
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:47:32
User entered 'Insomnia'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '10'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'as needed (PRN)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:19:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:40:42
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	18 Aug 2020 14:40:42
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:40:42

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:27:35
Data point term sent to Coder	System	04 Nov 2020 00:26:12
Coding entries removed.	Matthew Musikanth	04 Nov 2020 00:25:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:31:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
Data point term sent to Coder	System	01 Oct 2020 20:56:28
User entered 'Tylenol'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:57:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 22:54:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 18:14:38

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 06:50:12
	Matthew Musikanth	04 Nov 2020 00:25:26
	(b) (4)	
User entered 'Pain at injection site' reason for change: Data Entry Error	Matthew Musikanth	04 Nov 2020 00:25:26
	(b) (4)	
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 02:33:56
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 02:33:50
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'headache'	Matthew Musikanth	01 Oct 2020 20:56:04
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '500'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '09 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered '09 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:01:25
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'incorrect indication, updated. ' (Site from DM).	Matthew Musikanth (b) (4)	04 Nov 2020 00:25:37
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Headache in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 02:34:02
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:31:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User entered empty.	System	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User entered empty.	System	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:37
User entered empty.	System	01 Oct 2020 20:56:04

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 08:26:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 08:26:17
Data point term sent to Coder	System	08 Oct 2020 20:29:46
User entered 'Levaquin'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:40
User entered 'No (N)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:42
User entered 'Pleural Effusion'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:44
User entered '750'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:45
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:46
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:48
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:49
User entered 'q48hr'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:51
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:53
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:55
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:56
User entered '0'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:49:58
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 22:44:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:50:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 22:44:53
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:50:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User entered empty.	System	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User entered empty.	System	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:43
User entered empty.	System	08 Oct 2020 20:28:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:52:39
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) (b) (4)	21 Oct 2020 16:44:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:44:31
Data point term sent to Coder	System	21 Oct 2020 16:44:00
User entered 'Aspirin'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'Cardiac Event Prophylaxis'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered '81'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:52
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:43:30

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:53:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:45:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:45:34
Data point term sent to Coder	System	21 Oct 2020 16:45:02
User entered 'Eliquis'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'CAD'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered '5'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:54
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:44:08

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:53:33
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 16:46:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 16:46:41
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 16:46:04
User entered 'Atenolol'	Matthew Musikanth	21 Oct 2020 16:45:19
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 22:55:17
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'medication change not due to worsening of hypertension' (Site from DM).	Matthew Musikanth (b) (4)	18 Dec 2020 18:24:22
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:51:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'Hypertension'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered '50'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:21:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:45:19

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE, PRODUCTSYNONYM: BUMEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:48:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:48:35
Data point term sent to Coder	System	21 Oct 2020 16:48:06
User entered 'Bumex'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:42
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:43
User entered 'Severe Coronary Artery Disease'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:44
User entered 'I'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:47
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:48
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:50
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:51
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:52
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:54
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:56
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:54:58
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:15
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:20:13
Query 'Please provide source.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	27 Oct 2020 23:16:49
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:54:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:17
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:55:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User entered '1'	System	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User entered '1'	System	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:10
User entered '804 (804)'	System	21 Oct 2020 16:47:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:55:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 16:50:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 16:50:49
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 16:49:08
User entered 'Zetia'	Matthew Musikanth	21 Oct 2020 16:48:39
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'Hypercholesterolemia'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered '10'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:48:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:57:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:46
Data point term sent to Coder	System	21 Oct 2020 16:50:08
User entered 'Amiodarone'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'CAD'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered '400'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User entered '2'	System	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User entered '1'	System	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:22
User entered '804 (804)'	System	21 Oct 2020 16:49:34

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:57:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:47
Data point term sent to Coder	System	21 Oct 2020 16:51:10
User entered 'amiodarone'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'CAD'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered '200'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered '03 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered '17 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User entered '2'	System	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User entered '1'	System	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:15
User entered '804 (804)'	System	21 Oct 2020 16:50:18

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:03:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:04:47
Data point term sent to Coder	System	21 Oct 2020 16:51:09
User entered 'amiodarone'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'CAD'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered '200'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered '18 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:39
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:50:51

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:03:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:10:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:10:43
Data point term sent to Coder	System	21 Oct 2020 16:52:11
User entered 'Colchicine'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'In relation to CAD leading to coronary artery bypass surgery SAE. ' (Site from DM).	(b) (4), (b) (6) Matthew Musikanth (b) (4)	29 Dec 2020 04:20:16 18 Dec 2020 18:22:31
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:51:52
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'CAD'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered '.3'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:42
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:51:52

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
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)	30 Oct 2020 03:46:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:46:14
	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 20:24:19
Coding entries removed.	Natalie Moy (b) (4)	28 Oct 2020 20:23:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:04:55
	(b) (4)	
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)	21 Oct 2020 16:55:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 16:55:41
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 16:54:15
User entered 'Gabapentin'	Matthew Musikanth	21 Oct 2020 16:53:47
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:26
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:23:31
User entered 'carpal tunnel' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 20:23:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'Osteoarthritis'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered '300'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'un UNK 2014'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:53:47

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:05:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:56:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:56:33
Data point term sent to Coder	System	21 Oct 2020 16:55:19
User entered 'Levothyroxine'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'Hypothyroidism'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered '100'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'mcg'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:54:35

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:06:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:59:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:59:36
Data point term sent to Coder	System	21 Oct 2020 16:58:24
User entered 'Potassium chloride'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'Severe Coronary Artery Disease'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered '10'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'mEq'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:20:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User entered '1'	System	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User entered '1'	System	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:29
User entered '804 (804)'	System	21 Oct 2020 16:58:22

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:08:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 04:57:24
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 04:57:24
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:16:09
User entered 'Tramadol'	Matthew Musikanth	21 Oct 2020 17:15:45
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'Post Op Pain Management'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered '50'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'q4hr prn'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:50
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:15:45

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:09:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 11:08:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 11:08:33
Data point term sent to Coder	System	21 Oct 2020 17:17:13
User entered 'Docusate Sodium'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 04:20:28
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'In relation to SAE of coronary artery bypass' (Site from DM).	Matthew Musikanth (b) (4)	18 Dec 2020 18:23:17
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:53:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'Severe Coronary Artery Disease'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered '250'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 03:10:04
	(b) (4), (b) (6)	18 Feb 2021 22:36:15
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:54:22
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:54:16
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:54:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 10:33:38
	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
User closed query 'Per source end date is not indicate. Please reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:36:26 18 Feb 2021 22:36:21
Query 'Per source end date is not indicate. Please reconcile. ' answered with 'updated in source ' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 19:36:55
User opened query 'Per source end date is not indicate. Please reconcile. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:14:47 28 Jan 2021 16:54:16
User entered '24 Sep 2020' reason for change: Data Entry Error DataPoint Verified.	Natalie Moy (b) (4) (b) (4), (b) (6)	28 Jan 2021 16:54:16 27 Oct 2020 23:11:45
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:11:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User entered '2'	System	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User entered '1'	System	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:57
User entered '804 (804)'	System	21 Oct 2020 17:16:39

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:02:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 13:36:33
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 13:36:33
Data point term sent to Coder	System	06 Apr 2021 15:22:55
User closed query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	06 Apr 2021 15:22:21
Query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated' (Site from System).	Brenda Grande (b) (4) (b) (4)	06 Apr 2021 15:22:21
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	06 Apr 2021 15:21:59
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	06 Apr 2021 15:21:59
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	06 Apr 2021 15:21:59
User entered 'EXCEDRIN(acetaminophen, aspirin, caffeine)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	06 Apr 2021 15:21:59
User opened query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:33:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

2332 of 2595

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:56:53
User closed query 'Please confirm spelling.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:56:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:56:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:56:30
Data point term sent to Coder	System	27 Oct 2020 23:55:47
Query 'Please confirm spelling.' answered with 'UPdated' (Site from CRA).	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:34
DataPoint Un-verified.	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:26
Coding entries removed.	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:26
User entered 'EXcedrin' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:26
User opened query 'Please confirm spelling.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:32:24
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:09:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:46:44

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Oct 2020 17:46:44
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	21 Oct 2020 17:45:18
User entered 'Exedrin'	Matthew Musikanth	21 Oct 2020 17:44:50
	(b) (4)	

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'Headache'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:56:59
User closed query 'Please clarify. Source indicates dose of 250 mg. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:56:58
Query 'Please clarify. Source indicates dose of 250 mg. Please confirm and update as necessary.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:37
DataPoint Un-verified.	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:26
User entered '250' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 23:55:26
User opened query 'Please clarify. Source indicates dose of 250 mg. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:11:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered '325'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered empty.	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered '11 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered '0'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered '11 Sep 2020'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:10:21
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User entered empty.	System	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User entered empty.	System	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:15:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:32:02
User entered empty.	System	21 Oct 2020 17:44:50

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:15:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:26:50
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:26:09

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:15:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:14
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	25 Sep 2020 21:26:25

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:15:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:16
User entered 'CABG x3'	Matthew Musikanth (b) (4)	25 Sep 2020 21:26:25

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:51
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	25 Sep 2020 21:26:25

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:15:39

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:51
User entered empty.	Matthew Musikanth (b) (4)	25 Sep 2020 21:26:25

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:15:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:54
User entered '02 Oct 2020'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:05

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:15:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:32
User entered 'Left Chest Tube'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:05

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:54
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:05

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:15:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:54
User entered empty.	Matthew Musikanth (b) (4)	08 Oct 2020 20:28:05

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:15:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:58
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	19 Oct 2020 21:51:53

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:15:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:44
User entered 'Angiogram'	Matthew Musikanth (b) (4)	19 Oct 2020 21:51:53

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:15:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:58
User entered 'Medical History (MH)'	Matthew Musikanth (b) (4)	19 Oct 2020 21:51:53

US3112164

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:15:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:22:58
User entered empty.	Matthew Musikanth (b) (4)	19 Oct 2020 21:51:53

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered '28/Sep/2020 08:44'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '09/Oct/2020 13:05'	System	09 Oct 2020 13:05:57

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:13:09
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 13:05:57

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '09/Oct/2020 13:13'	System	09 Oct 2020 13:13:20

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:30:33
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 13:13:20

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '13/Oct/2020 14:30'	System	13 Oct 2020 14:30:44

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 18:16:02
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 14:30:44

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '20/Oct/2020 14:16'	System	20 Oct 2020 18:16:30

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:54:09
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 18:16:30

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '29/Oct/2020 12:54'	System	29 Oct 2020 16:54:22

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 21:49:56
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 16:54:22

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '10/Nov/2020 21:50'	System	10 Nov 2020 21:50:11

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:35:48
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 21:50:11

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '11/Jan/2021 15:35'	System	11 Jan 2021 20:36:00

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 17:02:54
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 20:36:00

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '04/Feb/2021 12:03'	System	04 Feb 2021 17:03:25

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 17:03:25

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '16/Feb/2021 11:27'	System	16 Feb 2021 16:27:11

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 16:27:11

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:15:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '16/Feb/2021 11:25'	System	16 Feb 2021 16:25:18

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 16:25:18

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:09:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'USA-US062-2020-MRNA-1273-P301000002'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'No (N)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Yes (Y)'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Laurie'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'Han-Conrad'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '9040 Friars Rd St 540'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'San Diego'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered 'CA'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 12:44:11
User entered '92108'	System	28 Sep 2020 12:43:07

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:05:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:42:26
User entered 'US'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:15:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Feb 2021 16:27:11
User entered '10'	System	16 Feb 2021 16:25:18
User entered '9'	System	04 Feb 2021 17:03:25
User entered '8'	System	11 Jan 2021 20:36:00
User entered '7'	System	10 Nov 2020 21:50:11
User entered '6'	System	29 Oct 2020 16:54:22
User entered '5'	System	20 Oct 2020 18:16:30
User entered '4'	System	13 Oct 2020 14:30:44
User entered '3'	System	09 Oct 2020 13:13:20
User entered '2'	System	09 Oct 2020 13:05:57
User entered '1'	System	28 Sep 2020 12:44:17

US3112164

Folder: SAE USA-US062-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:15:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:09:09
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:26:38
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 16:25:18