

US3172114 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:37:05

All time stamps listed in this document are displayed in GMT

US3172114

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:29:59

Generated On: 09 Jun 2021 15:37:05

Participant ID

US3172114

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

US3172114

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172114

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
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	False
Black	True
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

US3172114

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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

US3172114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3172114

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Were any significant conditions reported?

Yes ☒
No ☐

US3172114

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172114

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172114

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172114

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	RIGHT HIP FRACTURE
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3172114

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	RIGHT HIP SURGERY
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3172114

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172114

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172114

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:40
Height (xxx.x)	179.2 cm
Weight (xxx.x)	89.9 kg
BMI (xxx.x)	27.99521 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172114

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

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.

US3172114

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3172114

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3172114

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3172114

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 143863

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 ☒

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Height	ND - Not Done
Weight	ND - Not Done

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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)	14 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:00
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:22
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 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)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3172114

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 13:37 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 13:37

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

US3172114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 14 AUG 2020

Collection time (00:00-23:59) 13:10 (24 HR)

Collection date and time (derived) 14 AUG 2020 13:10

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:07	14 AUG 2020 13:07
Nasopharyngeal Swab 2	No		

US3172114

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:11

PC Open Date & Time

14 AUG 2020 13:57

PC Close Date & Time

14 AUG 2020 16:27

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 96.9 °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	15 AUG 2020 01:51
PC Open Date & Time	14 AUG 2020 17:22
PC Close Date & Time	15 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

96.9 °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

15 AUG 2020 19:44

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

16 AUG 2020 17:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 17 AUG 2020 17:17

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

19 AUG 2020 18:24

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

96.9 °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

20 AUG 2020 19:33

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:12

PC Open Date & Time

14 AUG 2020 13:57

PC Close Date & Time

14 AUG 2020 16:27

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

15 AUG 2020 01:52

PC Open Date & Time

14 AUG 2020 17:22

PC Close Date & Time

15 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

15 AUG 2020 19:46

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

16 AUG 2020 17:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

17 AUG 2020 17:17

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

18 AUG 2020 18:09

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

19 AUG 2020 18:24

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

20 AUG 2020 19:34

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 14:12
PC Open Date & Time	14 AUG 2020 13:57
PC Close Date & Time	14 AUG 2020 16:27

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 17:22

PC Close Date & Time

15 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 ☒

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:45
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

50 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:57
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

52 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

54 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

56 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 18:25
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

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)

58 of 2608

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:34
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3172114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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

Visit date (dd MMM yyyy)	16 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:20
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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)	16 SEP 2020
Time of assessment (00:00-23:59)	14:44 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:44
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3172114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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) 16 SEP 2020

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

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

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

US3172114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	13:18 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 SEP 2020 13:18
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US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:17	16 SEP 2020 13:17
Nasopharyngeal Swab 2	No		

US3172114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

16 SEP 2020 14:43

PC Open Date & Time

16 SEP 2020 14:34

PC Close Date & Time

16 SEP 2020 17:04

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 97.3 °F

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

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

PC Time Stamp	16 SEP 2020 17:59
PC Open Date & Time	16 SEP 2020 17:59
PC Close Date & Time	17 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 18:54

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 18:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 18:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 18:09

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 18:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

16 SEP 2020 14:43

PC Open Date & Time

16 SEP 2020 14:34

PC Close Date & Time

16 SEP 2020 17:04

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

16 SEP 2020 18:00

PC Open Date & Time

16 SEP 2020 17:59

PC Close Date & Time

17 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

17 SEP 2020 18:54

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

18 SEP 2020 18:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

19 SEP 2020 18:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

20 SEP 2020 20:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

21 SEP 2020 18:09

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

22 SEP 2020 18:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:44
PC Open Date & Time	16 SEP 2020 14:34
PC Close Date & Time	16 SEP 2020 17:04

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:00
PC Open Date & Time	16 SEP 2020 17:59
PC Close Date & Time	17 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:55
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

96 of 2608

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 18:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 ☒

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 18:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

100 of 2608

EAB) (1725)

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:53
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 ☒

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 18:09
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 ☒

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 18:41
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3172114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments UNABLE TO CONTACT. LEFT
MESSAGE.

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3172114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

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 _____

US3172114

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:04
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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.

US3172114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

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

Collection date (dd MMM yyyy)	12 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:24 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 OCT 2020 11:24
------------------------------------	-------------------

US3172114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:03

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 17:41:59

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 23:24:26

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 15:52:19

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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	18 NOV 2020 07:51:49
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 14:18:48

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

25 JAN 2021 07:15:56

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

01 FEB 2021 11:07:51

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 FEB 2021 00:34:37
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:01:55

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

28 FEB 2021 19:22:55

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

09 MAR 2021 22:13:29

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 08:33:42

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

28 MAR 2021 21:56:22

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

05 APR 2021 08:28:44

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

11 APR 2021 13:46:25

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 APR 2021 11:16:03
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 <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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 APR 2021 08:17:54
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 <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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	10 MAR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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°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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3172114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:37:05

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		27 FEB 2021 18:09:58

US3172114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

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

Visit date (dd MMM yyyy)	16 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:04:23

Generated On: 09 Jun 2021 15:37:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 12:24
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

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.

US3172114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

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

Collection date (dd MMM yyyy)	16 MAR 2021
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Collection time (00:00-23:59)	13:52 (24 HR)
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Collection date and time (derived)	16 MAR 2021 13:52
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US3172114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172114

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172114

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172114

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:37:05

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"/>

US3172114

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:37:05

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172114

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:30:00

Generated On: 09 Jun 2021 15:37:05

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 29 JAN 2021

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

Folder OID UNBLND_DECIDE

US3172114

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:04:22

Generated On: 09 Jun 2021 15:37:05

Date of updated informed consent (dd MMM yyyy) 06 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 29 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3172114

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:30:00

Generated On: 09 Jun 2021 15:37:05

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 29 JAN 2021

Collection time (00:00-23:59) 10:30 (24 HR)

Collection date and time (derived) 29 JAN 2021 10:30

US3172114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 15:29:59

Generated On: 09 Jun 2021 15:37:05

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

Collection date (dd MMM yyyy)	29 JAN 2021
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Collection time (00:00 - 23:59)	10:31
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Collection Date and Time (derived)	29 JAN 2021 10:31
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US3172114

Folder: **Unscheduled 14 Dec 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Visit Date	14 DEC 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 14:06
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:30:02

Generated On: 09 Jun 2021 15:37:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3172114

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 15:29:59

Generated On: 09 Jun 2021 15:37:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

AEID	USA-US118-2020-MRNA-1273-P30 1000013
Adverse event	SYNCOPE AND COLLAPSE (PRIMARY)
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)	15 NOV 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)	17 NOV 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	15 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	338 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

SUBJECT RETURNED THIS
AFTERNOON AFTER BEING
HERE TO DROP DISCHARGE
INSTRUCTIONS FOR ADM FROM
4DEC-11DEC AND DURING
UNSCH VISIT HE DISCLOSED
HAD ANOTHER ADMISSION ON
15NOV-18NOV. AT THE SAME
UM HOSPITAL THAT HE WENT
DUE TO TRANSIENT
LOOSENING OF CONSCIENCE
THEN AND NOW ON 4DEC. HE
DIDN'T HAVE ANY PARALYSIS,
MUSCLE WEAKNESS OR OTHER
MOTOR OR SENSORIAL
SYMPTOMS. PENDING
MEDICAL RECORDS FOR BOTH
ADM. TODAY HE IS
ASYMPTOMATIC WITH NO
SEQUELS OBSERVED WITH A
NORMAL PHYSICAL EXAM
INCLUDING NEUROLOGIC.
COVID 19 ACCULA RNA NAAT
15NOV2020 NOT DETECTED.
15NOV2020 TROPONIN T <0.01
REF RANGE: 0.00-0.06 NG/ML.
EKG REPORT 15NOV2020
RESULT: NORMAL SINUS
RHYTHM, NONSPECIFIC T
WAVE ABNORMALITY,
ABNORMAL ECG, WHEN
COMPARED WITH ECG OF
01NOV2020, NONSPECIFIC T
WAVE ABNORMALITY NOW
EVIDENT IN INFERIOR LEADS,
NONSPECIFIC T WAVE
ABNORMALITY NOW EVIDENT

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

IN LATERAL LEADS. ECHO 2D
DOPPLER-COLOR FLOW
16NOV2020 INTERPRETATION:
THERE IS MILD CONCENTRIC
LEFT VENTRICULAR
HYPERTROPHY, LEFT
VENTRICULAR SYSTOLIC
FUNCTION IS NORMAL,
EJECTION FRACTION= 60-65%,
GRADE I DIASTOLIC
DYSFUNCTION, (ABNORMAL
RELAXATION PATTERN), RIGHT
VENTRICULAR SYSTOLIC
PRESSURE IS NORMAL, THERE
IS NO PERICARDIAL EFFUSION.
CT HEAD WITHOUT CONTRAST
15NOV2020 FINDINGS: THERE IS
ADVANCED PARANASAL SINUS
DISEASE WITH MUCOSAL
THICKENING AND
OPACIFICATION FRONTAL
SINUSES ARE NEARLY
COMPLETELY OPACIFIED WITH
SMALL LEFT FRONTAL SINUS
FLUID LEVEL SUGGESTED.
RIGHT MAXILLARY SINUS
FLUID LEVEL ALSO
SUGGESTED. THE MASTOID AIR
CELLS ARE WITHOUT
SUBSTANTIAL ABNORMALITY.
NO SUSPICIOUS CALVARIAL
LESIONS. ACUTE ON CHRONIC
WIDESPREAD PARANASAL
SINUSITIS. CHEST XRAY AP
ONLY 15NOV2020 FINDINGS:
THERE IS NORMAL
CARDIOMEDIASTINAL

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

CONTOUR. THE LUNGS ARE
WELL EXPANDED AND APPEAR
CLEAR WITH THE EXCEPTION
OF SWOME PERSISTENT SMALL
CLUSTERED NODULAR
OPACITIES PROJECTING OVER
THE LATERAL ASPECT OF THE
LEFT MIDLUNG, BUT CANNOT
EXCLUDE THAT THIS IS WITHIN
THE OVERLYING RIB. NO
PLEURAL EFFUSION. NO
PNEUMOTHORAX. XRAY
FINDING NOT COMPLETED NO
MORE SPACE.

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

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

AEID	USA-US118-2020-MRNA-1273-P30 1000014
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 DEC 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)	11 DEC 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	11 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

SUBJECT SEEN COMING
WALKING BY HIMSELF TO SITE
THIS MORNING. JUST LEFT
DISCHARGE INSTRUCTIONS
WITH COORDINATOR SAYING
HE WAS ADMITTED TO
UNIVERSITY OF MIAMI
HOSPITAL AND COULDN'T
WAIT TO SEE AN
INVESTIGATOR. SUBJECT
CALLED TO EMERGENCY
CONTACT. HE IS PROVIDING US
HIS PRIMARY PHONE NUMBER
AND SPOKE WITH EMERGENCY
CONTACT WHO SAID HE IS
NOT THERE AT THIS TIME.
MEDICAL RECORDS TO BE
REQUESTED. CAROTID
ULTRASOUND 05DEC2020
IMPRESSION: NO
HEMODYNAMICALLY
SIGNIFICANT LESIONS INT HE
RICA (LESS THAN 59%
STENOSIS). COLOR DUPLEX
ULTRASOUND EVALUATION
DEMONSTRATES A PATENT
CAROTID SYSTEM WITH
MINIMAL SPECTRAL
BROADENING. MRI 07DEC2020
IMPRESSION: 1. SEVERE
PANSINUSITIS AND RIGHT
MASTOID DISEASE.
SECRETIONS DEMONSTRATED
LOW T2 SIGNAL CENTRALLY
WHICH COULD BE AN
INDICATION OF CHRONIC
INSPISSATION VERSUS FUNGAL

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

COLONIZATION OF
SECRETIONS. 2.AGING BRAIN
WITH SIGNS OF
PREVENTRICULAR AND
JUXTACORTICAL ISCHEMIC
LEUKOMALACIA AS WELL AS
SMALL OLD LACUNAR
INFARCTIONS IN BILATERAL
PERITIGONAL WHITE MATTER
REGIONS. 3.NO SIGNS OF
FOCAL BRAIN MASSES, MASS
EFFECT, HYDROCEPHALUS OR
ABNORMAL EXTRA-AXIAL
COLLECTIONS. NO ABNORMAL
INTRACRANIAL
ENHANCEMENT. THE BRAIN
DIFFUSION IS NORMAL. 4.
BRAIN MRA SHOWING NO
AREAS OF VASCULAR
CRITICAL STENOSIS OR
ANEURYSM MEASURING OVER
0.25CM IN THE INTRACRANIAL
SUPRA OR INFRATENTORIAL
ARTERIAL VASCULATURE
VISUALIZED. COVID 19
ACCUA RNA NAAT 04DEC2020
NOT DETECTED. 04DEC2021
HEMOGLOBIN 10.9L REF
RANGE: 13.3-16.3 G/DL AND
HEMATOCRIT 33.0L REF
RANGE: 39.0-47.1%. EKG
REPORT 04DEC2020 INVERTED
T WAVES IN INFERIOR LEADS
II, III, AVF AND LATERAL
LEADS V5 V6. ABNORMAL EKG
WITHOUT EVIDENCE OF STEMI.
NEGATIVE TROPONIN.

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

<hr/>		TOXICOLOGY SCREEN
		07DEC2020 COCAINE
		METABOLITES, URINE-
		RESULT: POSITIVE.
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)		1
<hr/>		
Medically Attended AE Derived (CSA Programming Field Only)		0
<hr/>		
Admitted to ICU Derived (CSA Programming Field Only)		0
<hr/>		

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

AEID	USA-US118-2020-MRNA-1273-P30 1000013
Adverse event	ACUTE KIDNEY INJURY
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)	15 NOV 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)	17 NOV 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	15 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

SUBJECT THAT IN THE COURSE
OF ADMISSION DUE TO
SYNCOPE EPISODE HAD A
CREATININE OF 1.65 REF
RANGE: 0.4-1.1 MG/DL AND GFR
51 >59 ML/MIN/1.73M2.
CONSISTENT WITH ACUTE
KIDNEY FAILURE SECONDARY
TO DEHYDRATION THAT
RESOLVED BY 17NOV WITH
CREATININE LEVELS OF 1.19
REF RANGE: 0.4-1.1 MG/DL AND
GFR IN 75 REF RANGE: >59
ML/MIN/1.73M2. COVID 19
ACCULA RNA NAAT 15NOV2020
NOT DETECTED. EKG REPORT
15NOV2020 RESULT: NORMAL
SINUS RHYTHM, NONSPECIFIC
T WAVE ABNORMALITY,
ABNORMAL ECG, WHEN
COMPARED WITH ECG OF
01NOV2020, NONSPECIFIC T
WAVE ABNORMALITY NOW
EVIDENT IN INFERIOR LEADS,
NONSPECIFIC T WAVE
ABNORMALITY NOW EVIDENT
IN LATERAL LEADS. ECHO 2D
DOPPLER-COLOR FLOW
16NOV2020 INTERPRETATION:
THERE IS MILD CONCENTRIC
LEFT VENTRICULAR
HYPERTROPHY, LEFT
VENTRICULAR SYSTOLIC
FUNCTION IS NORMAL,
EJECTION FRACTION= 60-65%,
GRADE I DIASTOLIC
DYSFUNCTION, (ABNORMAL

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

RELAXATION PATTERN), RIGHT
VENTRICULAR SYSTOLIC
PRESSURE IS NORMAL, THERE
IS NO PERICARDIAL EFFUSION.
CT HEAD WITHOUT CONTRAST
15NOV2020 FINDINGS: THERE IS
ADVANCED PARANASAL SINUS
DISEASE WITH MUCOSAL
THICKENING AND
OPACIFICATION FRONTAL
SINUSES ARE NEARLY
COMPLETELY OPACIFIED WITH
SMALL LEFT FRONTAL SINUS
FLUID LEVEL SUGGESTED.
RIGHT MAXILLARY SINUS
FLUID LEVEL ALSO
SUGGESTED. THE MASTOID AIR
CELLS ARE WITHOUT
SUBSTANTIAL ABNORMALITY.
NO SUSPICIOUS CALVARIAL
LESIONS. ACUTE ON CHRONIC
WIDESPREAD PARANASAL
SINUSITIS. CHEST XRAY AP
ONLY 15NOV2020 FINDINGS:
THERE IS NORMAL
CARDIOMEDIASTINAL
CONTOUR. THE LUNGS ARE
WELL EXPANDED AND APPEAR
CLEAR WITH THE EXCEPTION
OF SOME PERSISTENT SMALL
CLUSTERED NODULAR
OPACITIES PROJECTING OVER
THE LATERAL ASPECT OF THE
LEFT MIDLUNG, BUT CANNOT
EXCLUDE THAT THIS IS WITHIN
THE OVERLYING RIB. NO
PLEURAL EFFUSION. NO

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

<hr/>		PNEUMOTHORAX. SCATTERED TYPICAL BONY DEGENERATIVE/CHRONIC CHANGES.NO ACUTE PROCESS SEEN.
<hr/>		
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	
<hr/>		

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

AEID	USA-US118-2020-MRNA-1273-P30 1000014
Adverse event	ACUTE KIDNEY INJURY
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)	04 DEC 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)	10 DEC 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	11 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 165 AND GFR 31 CONSISTENT WITH ACUTE KIDNEY FAILURE 2ND TO DEHYDRATION THAT RESOLVED BY 10DEC WITH CREATININE LEVELS OF 1.08 AND GFR IN 84.

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 DEC 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)	20 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	COPD EXACERBATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 DEC 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)	28 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	NORMOCYTIC ANEMIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	PANSINUSITIS
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)	15 NOV 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)	27 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

AEID

Adverse event

LOWER LIP SWELLING
WITHOUT AIRWAY
INVOLVEMENT

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

15 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

364 of 2608

EAB) (1725)

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	RIGHT INGUINAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

AEID	
Adverse event	SYNCOPE AND COLLAPSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 NOV 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)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:29:59

Generated On: 09 Jun 2021 15:37:05

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

Yes ☒

No ☐

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

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication LISINOPRIL

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)

373 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE (2
PUFFS)

Dose per administration 90

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)

375 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

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)

377 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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)	18 NOV 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 DEC 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication DICYCLOMINE

Prophylaxis Yes ☐
No ☒

Indication BLOATING

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)

381 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 DEC 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication FLUTICASONE / SALMETAROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 250/50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 DEC 2020	
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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

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)

385 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication LOPERAMIDE

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 NOV 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication FOLIC ACID

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 NOV 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication DYPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication LOWER LIP SWELLING

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication LOWER LIP SWELLING

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 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"/>

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐
No ☒

Indication COPD EXACERBATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

	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)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 DEC 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"/>

US3172114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:29:59

Generated On: 09 Jun 2021 15:37:05

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172114

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:37:05

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

US3172114

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:37:05

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 ☐

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/DEC/2020 10:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:56
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/MAR/2021 15:13
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 16:30
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/APR/2021 11:05
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/APR/2021 09:16
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/APR/2021 08:32
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/APR/2021 14:36
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/DEC/2020 10:03
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	01/MAR/2021 15:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 16:33
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/APR/2021 11:06
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/APR/2021 15:36
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

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 07:33:26

Generated On: 09 Jun 2021 15:37:05

SAEID	USA-US118-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/APR/2021 07:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3172114 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172114

Form: Participant Creation

Generated On: 09 Jun 2021 15:37:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'US3172114'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:17

US3172114

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:21

US3172114

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:18

US3172114

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[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 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:21

US3172114

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'SCRN'	System	17 Aug 2020 12:28:21

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:19

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '62'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'YEARS'	System	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '62'	System	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:17

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Aug 2020'	System	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2020'	System	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:26

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:18

US3172114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'I'	System	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:37:05

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:37:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:38

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:51:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:36:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:36:39
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Data entered in conmed log' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:35:56
Data point term sent to Coder	System	10 Sep 2020 18:35:54
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:35:36
User entered 'MODERATE ASTHMA' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:35:36
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 18:56:56

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:34:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:34:15
Data point term sent to Coder	System	17 Aug 2020 12:33:36
User entered 'ASTHMA'	Mariete Rendon (b) (4)	17 Aug 2020 12:32:58
	(b) (4)	

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 2015'	System	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2015'	System	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:32:58

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
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)	17 Aug 2020 12:34:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:34:15
Data point term sent to Coder	System	17 Aug 2020 12:33:37
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 2015'	System	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2015'	System	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:33:31

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:36:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:36:09
Data point term sent to Coder	System	17 Aug 2020 12:34:37
User entered 'DIABETES TYPE 2'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 2015'	System	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2015'	System	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	17 Aug 2020 12:34:07

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:04:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:04:18
Data point term sent to Coder	System	17 Aug 2020 12:35:38
User entered 'RIGHT HIP FRACTURE'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 1975'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 1975'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 1975'	System	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '1975'	System	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 1975'	System	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '1975'	System	17 Aug 2020 12:34:42

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Hip surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:32:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:32:31
Data point term sent to Coder	System	17 Aug 2020 12:35:38
User entered 'RIGHT HIP SURGERY'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 1975'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 1975'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 1975'	System	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '1975'	System	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 1975'	System	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '1975'	System	17 Aug 2020 12:35:01

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 16:00:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 16:00:29
Data point term sent to Coder	System	01 Feb 2021 15:59:35
User entered 'copd'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 2015'	System	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2015'	System	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	01 Feb 2021 15:58:44

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:42:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:42:31
Data point term sent to Coder	System	01 Feb 2021 20:42:05
User entered 'allergic rhinitis'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'un UNK 2007'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'Jan 2007'	System	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '2007'	System	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered empty.	System	01 Feb 2021 20:41:53

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11:40'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '14 Aug 2020 11:40'	System	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '179.2' cm	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59
DataPoint set to visible.	System	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '89.9' kg	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59
DataPoint set to visible.	System	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
Amendment Manager: User entered '27.99521'	System	16 Sep 2020 23:57:22
User entered '28.0'	System	17 Aug 2020 12:29:59
DataPoint set to visible.	System	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'kg/m2'	System	17 Aug 2020 12:29:59
DataPoint set to visible.	System	14 Aug 2020 17:42:36

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Data is required. Please provide.' (Site from System).	Ipsita Abalokita (b) (4) (b) (4)	02 Sep 2020 18:16:00
Query 'Data is required. Please provide.' answered with 'per guidelines, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 21:17:44
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 12:29:59
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'bpm'	System	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'breaths/min'	System	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'mmHg'	System	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'mmHg'	System	17 Aug 2020 12:29:59

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10

US3172114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10

US3172114

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:11:43
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:08

US3172114

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:11:43
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:08

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'RETIRED'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

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)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:28:48

US3172114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:22

US3172114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:22

US3172114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:22

US3172114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'VISIT1'	System	17 Aug 2020 12:36:22

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:30

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:34:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:34:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:24:30
User entered '143863' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:30

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:24:30

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

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)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:34:57
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:38

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

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)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:38

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:38

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:38

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:36:38

US3172114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:18:50

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '12:00' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:47:14
User entered '11:40'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '14 Aug 2020 12:00'	System	01 Sep 2020 13:47:14
User entered '14 Aug 2020 11:40'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '36.2' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:47:14
User entered '36.6' C	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '72' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:47:14
User entered '87'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'bpm'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'breaths/min'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 14:23:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ABNORMAL, NCS. Consistent with baseline hypertension. Missed today's dose, advised to take his hypertension meds every morning.' (Site from System).	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:48:33
User entered '157' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:47:14
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 12:32:15
User entered '179'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '88' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:47:14
User entered '89'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14:22' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:52:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 12:09:15
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 12:32:15
User entered '14:08'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '14 Aug 2020 14:22'	System	01 Sep 2020 13:52:27
User entered '14 Aug 2020 14:08'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '37.1' C	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '67'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'bpm'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'breaths/min'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 14:23:38
User entered '152' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:52:27
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'abnormal, NCS. part of baseline. subject forgot to take his BP meds this morning, advised to take every morning' (Site from System).	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:52:11
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 12:32:15
User entered '167'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '90'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Aug 2020 12:32:15

US3172114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:11:55
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:52:55

US3172114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:11:55
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:52:55

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '14 Aug 2020'	Mariete Rendon (b) (4)	14 Aug 2020 17:43:10
	(b) (4)	

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13:37'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '14 Aug 2020 13:37'	System	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'ONCE'	System	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 17:43:10

US3172114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:34

US3172114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:34

US3172114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13:10'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:34

US3172114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '14 Aug 2020 13:10'	System	17 Aug 2020 12:53:34

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13:07'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '14 Aug 2020 13:07'	System	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:02:55
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:02:55
User entered '13:07'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered empty.	System	17 Sep 2020 13:02:55
User entered '14 Aug 2020 13:07'	System	17 Aug 2020 12:53:50

US3172114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:54:07

US3172114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'I'	System	17 Aug 2020 12:54:07

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:11:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '85b050fa-66e9-439f-a13c-f990ec7ab6dd'	System	14 Aug 2020 18:11:53
User entered 'Yes (Y)'	System	14 Aug 2020 18:11:53

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:11:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '85b050fa-66e9-439f-a13c-f990ec7ab6dd'	System	14 Aug 2020 18:11:53
User entered '98.7'	System	14 Aug 2020 18:11:53

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:11:48', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '85b050fa-66e9-439f-a13c-f990ec7ab6dd'	System	14 Aug 2020 18:11:53
User entered 'No (N)'	System	14 Aug 2020 18:11:53

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:11:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '85b050fa-66e9-439f-a13c-f990ec7ab6dd'	System	14 Aug 2020 18:11:53
User entered '14 Aug 2020 14:11'	System	14 Aug 2020 18:11:53

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 13:57'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 16:27'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:51:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5d7746a2-3d0c-43aa-9086-7838a2525ff1'	System	15 Aug 2020 05:51:58
User entered 'Yes (Y)'	System	15 Aug 2020 05:51:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:51:38', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5d7746a2-3d0c-43aa-9086-7838a2525ff1'	System	15 Aug 2020 05:51:58
User entered '96.9'	System	15 Aug 2020 05:51:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:51:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5d7746a2-3d0c-43aa-9086-7838a2525ff1'	System	15 Aug 2020 05:51:58
User entered 'No (N)'	System	15 Aug 2020 05:51:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:51:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5d7746a2-3d0c-43aa-9086-7838a2525ff1'	System	15 Aug 2020 05:51:58
User entered '15 Aug 2020 01:51'	System	15 Aug 2020 05:51:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 2'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:43:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd65cc83-f6f2-4784-bd5d-aa210ad5ecb8'	System	15 Aug 2020 23:44:49
User entered 'Yes (Y)'	System	15 Aug 2020 23:44:49

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:44:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd65cc83-f6f2-4784-bd5d-aa210ad5ecb8'	System	15 Aug 2020 23:44:49
User entered '96.9'	System	15 Aug 2020 23:44:49

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:44:20', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd65cc83-f6f2-4784-bd5d-aa210ad5ecb8'	System	15 Aug 2020 23:44:49
User entered 'No (N)'	System	15 Aug 2020 23:44:49

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:44:43', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd65cc83-f6f2-4784-bd5d-aa210ad5ecb8'	System	15 Aug 2020 23:44:49
User entered '15 Aug 2020 19:44'	System	15 Aug 2020 23:44:49

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 3'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:55:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '56f6b30e-3167-49be-ba2c-8a4974b9897b'	System	16 Aug 2020 21:56:35
User entered 'Yes (Y)'	System	16 Aug 2020 21:56:35

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:02', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '56f6b30e-3167-49be-ba2c-8a4974b9897b' User entered '97.6'	System	16 Aug 2020 21:56:35
	System	16 Aug 2020 21:56:35

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '56f6b30e-3167-49be-ba2c-8a4974b9897b'	System	16 Aug 2020 21:56:35
User entered 'No (N)'	System	16 Aug 2020 21:56:35

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '56f6b30e-3167-49be-ba2c-8a4974b9897b'	System	16 Aug 2020 21:56:35
User entered '16 Aug 2020 17:56'	System	16 Aug 2020 21:56:35

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 4'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '9b342ccc-4c38-413d-918c-6d1e23565d73'	System	17 Aug 2020 21:17:36
User entered 'No (N)'	System	17 Aug 2020 21:17:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '9b342ccc-4c38-413d-918c-6d1e23565d73'	System	17 Aug 2020 21:17:36
User entered 'No (N)'	System	17 Aug 2020 21:17:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '9b342ccc-4c38-413d-918c-6d1e23565d73'	System	17 Aug 2020 21:17:36
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 21:17:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 5'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:18', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a069ec44-a289-405c-b89c-c5f6a5188d76'	System	18 Aug 2020 22:08:36
User entered 'Yes (Y)'	System	18 Aug 2020 22:08:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a069ec44-a289-405c-b89c-c5f6a5188d76'	System	18 Aug 2020 22:08:36
User entered '97.1'	System	18 Aug 2020 22:08:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:07:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a069ec44-a289-405c-b89c-c5f6a5188d76'	System	18 Aug 2020 22:08:36
User entered 'No (N)'	System	18 Aug 2020 22:08:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a069ec44-a289-405c-b89c-c5f6a5188d76'	System	18 Aug 2020 22:08:36
User entered '18 Aug 2020 18:08'	System	18 Aug 2020 22:08:36

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 6'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:23:38', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4cb22cbb-eaba-46f1-8904-cc6f6cbca86f'	System	19 Aug 2020 22:24:05
User entered 'Yes (Y)'	System	19 Aug 2020 22:24:05

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:23:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4cb22cbb-eaba-46f1-8904-cc6f6cbca86f' User entered '96.9'	System	19 Aug 2020 22:24:05
	System	19 Aug 2020 22:24:05

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:23:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4cb22cbb-eaba-46f1-8904-cc6f6cbca86f'	System	19 Aug 2020 22:24:05
User entered 'No (N)'	System	19 Aug 2020 22:24:05

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:02', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4cb22cbb-eaba-46f1-8904-cc6f6cbca86f'	System	19 Aug 2020 22:24:05
User entered '19 Aug 2020 18:24'	System	19 Aug 2020 22:24:05

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 7'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7398348c-ae73-4daf-b37f-8782593e2e8e'	System	20 Aug 2020 23:33:58
User entered 'Yes (Y)'	System	20 Aug 2020 23:33:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:42', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7398348c-ae73-4daf-b37f-8782593e2e8e'	System	20 Aug 2020 23:33:58
User entered '96.9'	System	20 Aug 2020 23:33:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:46', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7398348c-ae73-4daf-b37f-8782593e2e8e'	System	20 Aug 2020 23:33:58
User entered 'No (N)'	System	20 Aug 2020 23:33:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7398348c-ae73-4daf-b37f-8782593e2e8e'	System	20 Aug 2020 23:33:58
User entered '20 Aug 2020 19:33'	System	20 Aug 2020 23:33:58

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7c9f4e46-4014-40f7-ae57-4f817992bd50'	System	14 Aug 2020 18:12:09
User entered 'None (1)'	System	14 Aug 2020 18:12:09

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:02', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7c9f4e46-4014-40f7-ae57-4f817992bd50'	System	14 Aug 2020 18:12:09
User entered 'No (N)'	System	14 Aug 2020 18:12:09

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:04', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7c9f4e46-4014-40f7-ae57-4f817992bd50'	System	14 Aug 2020 18:12:09
User entered 'No (N)'	System	14 Aug 2020 18:12:09

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:05', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7c9f4e46-4014-40f7-ae57-4f817992bd50'	System	14 Aug 2020 18:12:09
User entered 'None (1)'	System	14 Aug 2020 18:12:09

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:07', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7c9f4e46-4014-40f7-ae57-4f817992bd50'	System	14 Aug 2020 18:12:09
User entered '14 Aug 2020 14:12'	System	14 Aug 2020 18:12:09

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 13:57'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 16:27'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:52:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbc2dfbe-5702-4e06-94a1-2721c97e7638'	System	15 Aug 2020 05:52:41
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 05:52:41

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:52:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbc2dfbe-5702-4e06-94a1-2721c97e7638'	System	15 Aug 2020 05:52:41
User entered 'No (N)'	System	15 Aug 2020 05:52:41

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:52:21', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbc2dfbe-5702-4e06-94a1-2721c97e7638'	System	15 Aug 2020 05:52:41
User entered 'No (N)'	System	15 Aug 2020 05:52:41

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:52:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbc2dfbe-5702-4e06-94a1-2721c97e7638'	System	15 Aug 2020 05:52:41
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 05:52:41

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T01:52:39', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbc2dfbe-5702-4e06-94a1-2721c97e7638'	System	15 Aug 2020 05:52:41
User entered '15 Aug 2020 01:52'	System	15 Aug 2020 05:52:41

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 2'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a5eb9c1e-b6d4-40c5-b8ab-cd4fb5d6b842'	System	15 Aug 2020 23:46:18
User entered 'None (1)'	System	15 Aug 2020 23:46:18

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a5eb9c1e-b6d4-40c5-b8ab-cd4fb5d6b842'	System	15 Aug 2020 23:46:18
User entered 'No (N)'	System	15 Aug 2020 23:46:18

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a5eb9c1e-b6d4-40c5-b8ab-cd4fb5d6b842'	System	15 Aug 2020 23:46:18
User entered 'No (N)'	System	15 Aug 2020 23:46:18

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:46:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a5eb9c1e-b6d4-40c5-b8ab-cd4fb5d6b842'	System	15 Aug 2020 23:46:18
User entered 'None (1)'	System	15 Aug 2020 23:46:18

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:46:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a5eb9c1e-b6d4-40c5-b8ab-cd4fb5d6b842'	System	15 Aug 2020 23:46:18
User entered '15 Aug 2020 19:46'	System	15 Aug 2020 23:46:18

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 3'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '6d1abd33-48cf-49b8-9e2e-587f16c7d39e'	System	16 Aug 2020 21:56:50
User entered 'None (1)'	System	16 Aug 2020 21:56:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:30', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '6d1abd33-48cf-49b8-9e2e-587f16c7d39e'	System	16 Aug 2020 21:56:50
User entered 'No (N)'	System	16 Aug 2020 21:56:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '6d1abd33-48cf-49b8-9e2e-587f16c7d39e'	System	16 Aug 2020 21:56:50
User entered 'No (N)'	System	16 Aug 2020 21:56:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:38', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '6d1abd33-48cf-49b8-9e2e-587f16c7d39e'	System	16 Aug 2020 21:56:50
User entered 'None (1)'	System	16 Aug 2020 21:56:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '6d1abd33-48cf-49b8-9e2e-587f16c7d39e'	System	16 Aug 2020 21:56:50
User entered '16 Aug 2020 17:56'	System	16 Aug 2020 21:56:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 4'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:37', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0b0c2258-7ce1-4853-9148-0f5989b1cdda'	System	17 Aug 2020 21:17:54
User entered 'None (1)'	System	17 Aug 2020 21:17:54

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:39', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0b0c2258-7ce1-4853-9148-0f5989b1cdda'	System	17 Aug 2020 21:17:54
User entered 'No (N)'	System	17 Aug 2020 21:17:54

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:41', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0b0c2258-7ce1-4853-9148-0f5989b1cdda'	System	17 Aug 2020 21:17:54
User entered 'No (N)'	System	17 Aug 2020 21:17:54

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0b0c2258-7ce1-4853-9148-0f5989b1cdda'	System	17 Aug 2020 21:17:54
User entered 'None (1)'	System	17 Aug 2020 21:17:54

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:17:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0b0c2258-7ce1-4853-9148-0f5989b1cdda'	System	17 Aug 2020 21:17:54
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 21:17:54

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 5'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:48', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '43f6c08a-915b-42f8-8b54-93f43655d32d'	System	18 Aug 2020 22:09:03
User entered 'None (1)'	System	18 Aug 2020 22:09:03

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '43f6c08a-915b-42f8-8b54-93f43655d32d'	System	18 Aug 2020 22:09:03
User entered 'No (N)'	System	18 Aug 2020 22:09:03

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '43f6c08a-915b-42f8-8b54-93f43655d32d'	System	18 Aug 2020 22:09:03
User entered 'No (N)'	System	18 Aug 2020 22:09:03

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:08:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '43f6c08a-915b-42f8-8b54-93f43655d32d'	System	18 Aug 2020 22:09:03
User entered 'None (1)'	System	18 Aug 2020 22:09:03

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '43f6c08a-915b-42f8-8b54-93f43655d32d'	System	18 Aug 2020 22:09:03
User entered '18 Aug 2020 18:09'	System	18 Aug 2020 22:09:03

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 6'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'def7b71e-0037-4a65-8501-d834918bbb3f'	System	19 Aug 2020 22:24:50
User entered 'None (1)'	System	19 Aug 2020 22:24:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:37', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'def7b71e-0037-4a65-8501-d834918bbb3f'	System	19 Aug 2020 22:24:50
User entered 'No (N)'	System	19 Aug 2020 22:24:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'def7b71e-0037-4a65-8501-d834918bbb3f'	System	19 Aug 2020 22:24:50
User entered 'No (N)'	System	19 Aug 2020 22:24:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'def7b71e-0037-4a65-8501-d834918bbb3f'	System	19 Aug 2020 22:24:50
User entered 'None (1)'	System	19 Aug 2020 22:24:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:47', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'def7b71e-0037-4a65-8501-d834918bbb3f'	System	19 Aug 2020 22:24:50
User entered '19 Aug 2020 18:24'	System	19 Aug 2020 22:24:50

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 7'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '559604b7-6a42-4fd1-894e-d3b8acab4280'	System	20 Aug 2020 23:34:11
User entered 'None (1)'	System	20 Aug 2020 23:34:11

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:33:59', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '559604b7-6a42-4fd1-894e-d3b8acab4280'	System	20 Aug 2020 23:34:11
User entered 'No (N)'	System	20 Aug 2020 23:34:11

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '559604b7-6a42-4fd1-894e-d3b8acab4280'	System	20 Aug 2020 23:34:11
User entered 'No (N)'	System	20 Aug 2020 23:34:11

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:03', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '559604b7-6a42-4fd1-894e-d3b8acab4280'	System	20 Aug 2020 23:34:11
User entered 'None (1)'	System	20 Aug 2020 23:34:11

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:06', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '559604b7-6a42-4fd1-894e-d3b8acab4280'	System	20 Aug 2020 23:34:11
User entered '20 Aug 2020 19:34'	System	20 Aug 2020 23:34:11

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:13', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:18', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:20', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'None (0)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered 'No (N)'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-14T14:12:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1042ed4b-eb62-45ed-acd2-31ac6e86c3e1'	System	14 Aug 2020 18:12:26
User entered '14 Aug 2020 14:12'	System	14 Aug 2020 18:12:26

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 13:57'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 16:27'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 2'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:44:54', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:44:59', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:03', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:12', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'None (0)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:20', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered 'No (N)'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-15T19:45:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e863f238-14e2-4bd3-9f72-115c994b4f1a'	System	15 Aug 2020 23:45:36
User entered '15 Aug 2020 19:45'	System	15 Aug 2020 23:45:36

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 3'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:56:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:02', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:04', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:07', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:09', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'None (0)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered 'No (N)'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-16T17:57:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3b6e8040-451c-4319-b32e-78c41eaa5d74'	System	16 Aug 2020 21:57:22
User entered '16 Aug 2020 17:57'	System	16 Aug 2020 21:57:22

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 4'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:04', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:13', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'None (0)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered 'No (N)'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-17T17:18:26', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c69a8b0a-4a36-44b3-8bb5-767be0b65a85'	System	17 Aug 2020 21:18:28
User entered '17 Aug 2020 17:18'	System	17 Aug 2020 21:18:28

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 5'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:06', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:09', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:13', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'None (0)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:23', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered 'No (N)'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-18T18:09:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'db57b26b-d89c-473a-85dd-7dce909a9e03'	System	18 Aug 2020 22:09:32
User entered '18 Aug 2020 18:09'	System	18 Aug 2020 22:09:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 6'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:24:58', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:25:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:25:03', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:25:05', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'None (0)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:25:09', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered 'No (N)'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-19T18:25:12', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3383d38a-3fde-4932-aa63-c865eff7253c'	System	19 Aug 2020 22:25:14
User entered '19 Aug 2020 18:25'	System	19 Aug 2020 22:25:14

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 7'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:14', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:16', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:18', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:20', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'None (0)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:26', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered 'No (N)'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-08-20T19:34:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f706f2df-10a8-4800-b412-8f61319fdfe5'	System	20 Aug 2020 23:34:32
User entered '20 Aug 2020 19:34'	System	20 Aug 2020 23:34:32

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:43:10

US3172114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Aug 2020 19:29:24

US3172114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '24 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	24 Aug 2020 19:29:24

US3172114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	24 Aug 2020 19:29:24

US3172114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Aug 2020 19:29:24

US3172114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Aug 2020 19:29:48

US3172114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered 'I'	System	24 Aug 2020 19:29:48

US3172114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:33:53

US3172114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '28 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:33:53

US3172114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	31 Aug 2020 20:33:53
	(b) (4)	

US3172114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:33:53

US3172114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:33:58

US3172114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered 'I'	System	31 Aug 2020 20:33:58

US3172114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:31:41

US3172114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '04 Sep 2020'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:31:41

US3172114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:31:41

US3172114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:31:41

US3172114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:31:46

US3172114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered 'I'	System	08 Sep 2020 14:31:46

US3172114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:25:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:25:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:25:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'VISIT2'	System	17 Sep 2020 19:25:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '11:20'	Mariete Rendon (b) (4)	17 Sep 2020 19:27:18
	(b) (4)	

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '16 Sep 2020 11:20'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '37.0' C	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '71'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'bpm'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'breaths/min'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '140'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '85'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '14:44'	Mariete Rendon (b) (4)	17 Sep 2020 19:27:18
	(b) (4)	

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '16 Sep 2020 14:44'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '37.2' C	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '74'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'bpm'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '15'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'breaths/min'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '139'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '87'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	17 Sep 2020 19:27:18

US3172114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:25

US3172114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:25

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14:14'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '16 Sep 2020 14:14'	System	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'ONCE'	System	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 18:26:17

US3172114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:38

US3172114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:38

US3172114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13:18'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:38

US3172114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '16 Sep 2020 13:18'	System	17 Sep 2020 19:27:38

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13:17'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '16 Sep 2020 13:17'	System	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered empty.	System	17 Sep 2020 19:27:48

US3172114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:27:53

US3172114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'I'	System	17 Sep 2020 19:27:53

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:42:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '60d3bd24-bad3-4abe-84b3-242f0111ba59'	System	16 Sep 2020 18:43:13
User entered 'Yes (Y)'	System	16 Sep 2020 18:43:13

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:42:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '60d3bd24-bad3-4abe-84b3-242f0111ba59' User entered '98.9'	System	16 Sep 2020 18:43:13
	System	16 Sep 2020 18:43:13

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '60d3bd24-bad3-4abe-84b3-242f0111ba59'	System	16 Sep 2020 18:43:13
User entered 'No (N)'	System	16 Sep 2020 18:43:13

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '60d3bd24-bad3-4abe-84b3-242f0111ba59'	System	16 Sep 2020 18:43:13
User entered '16 Sep 2020 14:43'	System	16 Sep 2020 18:43:13

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 14:34'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:04'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2c7e64c9-c9cd-4b63-b3a8-cbc47a868c9d'	System	16 Sep 2020 21:59:49
User entered 'Yes (Y)'	System	16 Sep 2020 21:59:49

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2c7e64c9-c9cd-4b63-b3a8-cbc47a868c9d'	System	16 Sep 2020 21:59:49
User entered '97.3'	System	16 Sep 2020 21:59:49

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2c7e64c9-c9cd-4b63-b3a8-cbc47a868c9d'	System	16 Sep 2020 21:59:49
User entered 'No (N)'	System	16 Sep 2020 21:59:49

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2c7e64c9-c9cd-4b63-b3a8-cbc47a868c9d'	System	16 Sep 2020 21:59:49
User entered '16 Sep 2020 17:59'	System	16 Sep 2020 21:59:49

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 2'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:14', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5521c9f2-ef90-4b88-8deb-06b6dafc7e6b'	System	17 Sep 2020 22:54:39
User entered 'Yes (Y)'	System	17 Sep 2020 22:54:39

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:25', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5521c9f2-ef90-4b88-8deb-06b6dafc7e6b'	System	17 Sep 2020 22:54:39
User entered '97.3'	System	17 Sep 2020 22:54:39

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5521c9f2-ef90-4b88-8deb-06b6dafc7e6b'	System	17 Sep 2020 22:54:39
User entered 'No (N)'	System	17 Sep 2020 22:54:39

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:34', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5521c9f2-ef90-4b88-8deb-06b6dafc7e6b'	System	17 Sep 2020 22:54:39
User entered '17 Sep 2020 18:54'	System	17 Sep 2020 22:54:39

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 3'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:09:39', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a82e15ee-2183-4134-b6a9-b129d18ecd40'	System	18 Sep 2020 22:10:10
User entered 'Yes (Y)'	System	18 Sep 2020 22:10:10

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:09:51', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a82e15ee-2183-4134-b6a9-b129d18ecd40'	System	18 Sep 2020 22:10:10
User entered '97.3'	System	18 Sep 2020 22:10:10

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:09:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a82e15ee-2183-4134-b6a9-b129d18ecd40'	System	18 Sep 2020 22:10:10
User entered 'No (N)'	System	18 Sep 2020 22:10:10

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:04', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'a82e15ee-2183-4134-b6a9-b129d18ecd40'	System	18 Sep 2020 22:10:10
User entered '18 Sep 2020 18:10'	System	18 Sep 2020 22:10:10

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 4'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:01:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ee2e8881-65c3-4de7-9b01-3a7039599c49'	System	19 Sep 2020 22:02:00
User entered 'Yes (Y)'	System	19 Sep 2020 22:02:00

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:01:48', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ee2e8881-65c3-4de7-9b01-3a7039599c49'	System	19 Sep 2020 22:02:00
User entered '97.1'	System	19 Sep 2020 22:02:00

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:01:51', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ee2e8881-65c3-4de7-9b01-3a7039599c49'	System	19 Sep 2020 22:02:00
User entered 'No (N)'	System	19 Sep 2020 22:02:00

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:01:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ee2e8881-65c3-4de7-9b01-3a7039599c49'	System	19 Sep 2020 22:02:00
User entered '19 Sep 2020 18:01'	System	19 Sep 2020 22:02:00

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 5'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c02e1344-d2bc-4472-b093-31a6bcf15646'	System	21 Sep 2020 00:53:26
User entered 'Yes (Y)'	System	21 Sep 2020 00:53:26

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:16', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c02e1344-d2bc-4472-b093-31a6bcf15646'	System	21 Sep 2020 00:53:26
User entered '97.1'	System	21 Sep 2020 00:53:26

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c02e1344-d2bc-4472-b093-31a6bcf15646'	System	21 Sep 2020 00:53:26
User entered 'No (N)'	System	21 Sep 2020 00:53:26

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'c02e1344-d2bc-4472-b093-31a6bcf15646'	System	21 Sep 2020 00:53:26
User entered '20 Sep 2020 20:53'	System	21 Sep 2020 00:53:26

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 6'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd5343e4-b27d-4ec4-abf8-1b646e6b944d'	System	21 Sep 2020 22:09:22
User entered 'Yes (Y)'	System	21 Sep 2020 22:09:22

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd5343e4-b27d-4ec4-abf8-1b646e6b944d'	System	21 Sep 2020 22:09:22
User entered '97.5'	System	21 Sep 2020 22:09:22

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd5343e4-b27d-4ec4-abf8-1b646e6b944d'	System	21 Sep 2020 22:09:22
User entered 'No (N)'	System	21 Sep 2020 22:09:22

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:18', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fd5343e4-b27d-4ec4-abf8-1b646e6b944d'	System	21 Sep 2020 22:09:22
User entered '21 Sep 2020 18:09'	System	21 Sep 2020 22:09:22

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 7'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:14', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7aa55bcb-1660-4c32-aab7-ad7da30223e1'	System	22 Sep 2020 22:40:33
User entered 'Yes (Y)'	System	22 Sep 2020 22:40:33

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7aa55bcb-1660-4c32-aab7-ad7da30223e1' User entered '97.1'	System	22 Sep 2020 22:40:33
	System	22 Sep 2020 22:40:33

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:26', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7aa55bcb-1660-4c32-aab7-ad7da30223e1'	System	22 Sep 2020 22:40:33
User entered 'No (N)'	System	22 Sep 2020 22:40:33

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7aa55bcb-1660-4c32-aab7-ad7da30223e1'	System	22 Sep 2020 22:40:33
User entered '22 Sep 2020 18:40'	System	22 Sep 2020 22:40:33

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:23', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '04c2a6c5-5158-48c0-9165-f43d1e51f15a'	System	16 Sep 2020 18:43:44
User entered 'None (1)'	System	16 Sep 2020 18:43:44

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '04c2a6c5-5158-48c0-9165-f43d1e51f15a'	System	16 Sep 2020 18:43:44
User entered 'No (N)'	System	16 Sep 2020 18:43:44

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '04c2a6c5-5158-48c0-9165-f43d1e51f15a'	System	16 Sep 2020 18:43:44
User entered 'No (N)'	System	16 Sep 2020 18:43:44

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:36', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '04c2a6c5-5158-48c0-9165-f43d1e51f15a'	System	16 Sep 2020 18:43:44
User entered 'None (1)'	System	16 Sep 2020 18:43:44

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:42', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '04c2a6c5-5158-48c0-9165-f43d1e51f15a'	System	16 Sep 2020 18:43:44
User entered '16 Sep 2020 14:43'	System	16 Sep 2020 18:43:44

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 14:34'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:04'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbaf756c-cfc7-4f72-9119-e49c87c5311d'	System	16 Sep 2020 22:00:08
User entered 'None (1)'	System	16 Sep 2020 22:00:08

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:54', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbaf756c-cfc7-4f72-9119-e49c87c5311d'	System	16 Sep 2020 22:00:08
User entered 'No (N)'	System	16 Sep 2020 22:00:08

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbaf756c-cfc7-4f72-9119-e49c87c5311d'	System	16 Sep 2020 22:00:08
User entered 'No (N)'	System	16 Sep 2020 22:00:08

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T17:59:58', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbaf756c-cfc7-4f72-9119-e49c87c5311d'	System	16 Sep 2020 22:00:08
User entered 'None (1)'	System	16 Sep 2020 22:00:08

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cbaf756c-cfc7-4f72-9119-e49c87c5311d'	System	16 Sep 2020 22:00:08
User entered '16 Sep 2020 18:00'	System	16 Sep 2020 22:00:08

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 2'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:39', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '452128c5-df29-4f63-9d2e-f54e46f61ad5'	System	17 Sep 2020 22:54:51
User entered 'None (1)'	System	17 Sep 2020 22:54:51

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:42', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '452128c5-df29-4f63-9d2e-f54e46f61ad5'	System	17 Sep 2020 22:54:51
User entered 'No (N)'	System	17 Sep 2020 22:54:51

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '452128c5-df29-4f63-9d2e-f54e46f61ad5'	System	17 Sep 2020 22:54:51
User entered 'No (N)'	System	17 Sep 2020 22:54:51

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:46', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '452128c5-df29-4f63-9d2e-f54e46f61ad5'	System	17 Sep 2020 22:54:51
User entered 'None (1)'	System	17 Sep 2020 22:54:51

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '452128c5-df29-4f63-9d2e-f54e46f61ad5'	System	17 Sep 2020 22:54:51
User entered '17 Sep 2020 18:54'	System	17 Sep 2020 22:54:51

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 3'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'adf4c3f8-4710-4c3d-a15f-5ccc37383cb7'	System	18 Sep 2020 22:10:21
User entered 'None (1)'	System	18 Sep 2020 22:10:21

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'adf4c3f8-4710-4c3d-a15f-5ccc37383cb7'	System	18 Sep 2020 22:10:21
User entered 'No (N)'	System	18 Sep 2020 22:10:21

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:12', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'adf4c3f8-4710-4c3d-a15f-5ccc37383cb7'	System	18 Sep 2020 22:10:21
User entered 'No (N)'	System	18 Sep 2020 22:10:21

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:14', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'adf4c3f8-4710-4c3d-a15f-5ccc37383cb7'	System	18 Sep 2020 22:10:21
User entered 'None (1)'	System	18 Sep 2020 22:10:21

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'adf4c3f8-4710-4c3d-a15f-5ccc37383cb7'	System	18 Sep 2020 22:10:21
User entered '18 Sep 2020 18:10'	System	18 Sep 2020 22:10:21

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 4'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1089ff89-02f2-4bd3-bc9b-e382ae6fd0f1'	System	19 Sep 2020 22:02:15
User entered 'None (1)'	System	19 Sep 2020 22:02:15

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:04', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1089ff89-02f2-4bd3-bc9b-e382ae6fd0f1'	System	19 Sep 2020 22:02:15
User entered 'No (N)'	System	19 Sep 2020 22:02:15

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:06', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1089ff89-02f2-4bd3-bc9b-e382ae6fd0f1'	System	19 Sep 2020 22:02:15
User entered 'No (N)'	System	19 Sep 2020 22:02:15

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1089ff89-02f2-4bd3-bc9b-e382ae6fd0f1'	System	19 Sep 2020 22:02:15
User entered 'None (1)'	System	19 Sep 2020 22:02:15

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:12', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1089ff89-02f2-4bd3-bc9b-e382ae6fd0f1'	System	19 Sep 2020 22:02:15
User entered '19 Sep 2020 18:02'	System	19 Sep 2020 22:02:15

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 5'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:26', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4b7e1ac5-5f65-4172-bf02-fd15402bb1b3'	System	21 Sep 2020 00:53:38
User entered 'None (1)'	System	21 Sep 2020 00:53:38

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4b7e1ac5-5f65-4172-bf02-fd15402bb1b3'	System	21 Sep 2020 00:53:38
User entered 'No (N)'	System	21 Sep 2020 00:53:38

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:30', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4b7e1ac5-5f65-4172-bf02-fd15402bb1b3'	System	21 Sep 2020 00:53:38
User entered 'No (N)'	System	21 Sep 2020 00:53:38

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4b7e1ac5-5f65-4172-bf02-fd15402bb1b3'	System	21 Sep 2020 00:53:38
User entered 'None (1)'	System	21 Sep 2020 00:53:38

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:35', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4b7e1ac5-5f65-4172-bf02-fd15402bb1b3'	System	21 Sep 2020 00:53:38
User entered '20 Sep 2020 20:53'	System	21 Sep 2020 00:53:38

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 6'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:23', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fc74ccdc-e5be-4312-9ace-9953a4c4a181'	System	21 Sep 2020 22:09:37
User entered 'None (1)'	System	21 Sep 2020 22:09:37

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:25', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fc74ccdc-e5be-4312-9ace-9953a4c4a181'	System	21 Sep 2020 22:09:37
User entered 'No (N)'	System	21 Sep 2020 22:09:37

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fc74ccdc-e5be-4312-9ace-9953a4c4a181'	System	21 Sep 2020 22:09:37
User entered 'No (N)'	System	21 Sep 2020 22:09:37

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:30', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fc74ccdc-e5be-4312-9ace-9953a4c4a181'	System	21 Sep 2020 22:09:37
User entered 'None (1)'	System	21 Sep 2020 22:09:37

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'fc74ccdc-e5be-4312-9ace-9953a4c4a181'	System	21 Sep 2020 22:09:37
User entered '21 Sep 2020 18:09'	System	21 Sep 2020 22:09:37

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 7'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:34', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '539ebf80-f6f1-4aa7-b7e7-e4459235ad20'	System	22 Sep 2020 22:40:50
User entered 'None (1)'	System	22 Sep 2020 22:40:50

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:36', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '539ebf80-f6f1-4aa7-b7e7-e4459235ad20'	System	22 Sep 2020 22:40:50
User entered 'No (N)'	System	22 Sep 2020 22:40:50

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:38', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '539ebf80-f6f1-4aa7-b7e7-e4459235ad20'	System	22 Sep 2020 22:40:50
User entered 'No (N)'	System	22 Sep 2020 22:40:50

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '539ebf80-f6f1-4aa7-b7e7-e4459235ad20'	System	22 Sep 2020 22:40:50
User entered 'None (1)'	System	22 Sep 2020 22:40:50

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '539ebf80-f6f1-4aa7-b7e7-e4459235ad20'	System	22 Sep 2020 22:40:50
User entered '22 Sep 2020 18:40'	System	22 Sep 2020 22:40:50

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:54', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:43:58', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:44:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered 'None (0)'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:44:02', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7'	System	16 Sep 2020 18:44:18
User entered 'No (N)'	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T14:44:13', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'e5831e11-fe30-466b-b146-a70a47a0b3e7' User entered '16 Sep 2020 14:44'	System	16 Sep 2020 18:44:18
	System	16 Sep 2020 18:44:18

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 14:34'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:04'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:16', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:21', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'None (0)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:31', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered 'No (N)'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-16T18:00:36', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'bfcc54a3-49de-41ea-8f46-03dcf8601b03'	System	16 Sep 2020 22:00:39
User entered '16 Sep 2020 18:00'	System	16 Sep 2020 22:00:39

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '16 Sep 2020 17:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 2'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:53', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:57', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:54:59', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:55:01', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:55:03', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'None (0)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:55:05', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered 'No (N)'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-17T18:55:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '76fc263d-8f41-46ff-9c98-113a07f43d37'	System	17 Sep 2020 22:55:12
User entered '17 Sep 2020 18:55'	System	17 Sep 2020 22:55:12

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 3'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:22', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:24', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:25', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:31', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'None (0)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:33', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered 'No (N)'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-18T18:10:37', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5f5b5d90-31e4-4bf4-aa68-882da95839fe'	System	18 Sep 2020 22:10:40
User entered '18 Sep 2020 18:10'	System	18 Sep 2020 22:10:40

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 4'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:17', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:21', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:23', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:25', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:27', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'None (0)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:29', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered 'No (N)'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-19T18:02:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '1fec723d-2caf-477c-8e6f-0488e07f85f0'	System	19 Sep 2020 22:02:37
User entered '19 Sep 2020 18:02'	System	19 Sep 2020 22:02:37

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 5'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:40', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:43', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:46', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:48', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'None (0)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:54', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered 'No (N)'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-20T20:53:58', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7f38e955-2cb6-4473-9b39-f579d7b6242a'	System	21 Sep 2020 00:54:03
User entered '20 Sep 2020 20:53'	System	21 Sep 2020 00:54:03

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 6'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:37', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:39', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:41', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:43', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:47', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'None (0)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered 'No (N)'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-21T18:09:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3f5388db-8369-4e30-922d-63a7c667f6d7'	System	21 Sep 2020 22:09:56
User entered '21 Sep 2020 18:09'	System	21 Sep 2020 22:09:56

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	16 Sep 2020 18:26:17
User entered 'Day 7'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:40:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:41:03', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:41:08', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:41:10', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'None (0)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:41:13', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered 'No (N)'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-09-22T18:41:15', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5add95d9-7ebe-4dec-b58d-aedde7c4e8bb'	System	22 Sep 2020 22:41:22
User entered '22 Sep 2020 18:41'	System	22 Sep 2020 22:41:22

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:26:17

US3172114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:26:17

US3172114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:45

US3172114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '23 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:45

US3172114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:45

US3172114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:45

US3172114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 14:47:51

US3172114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered 'I'	System	24 Sep 2020 14:47:51

US3172114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:55:20

US3172114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2 Oct 2020'	Mariete Rendon (b) (4)	06 Oct 2020 20:55:20
	(b) (4)	

US3172114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:55:20

US3172114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'unable to contact. left message.'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:55:20

US3172114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:57:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:56:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:55:23

US3172114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered empty.	System	12 Oct 2020 19:57:05
User entered 'I'	System	12 Oct 2020 19:56:28
User entered empty.	System	06 Oct 2020 20:55:23

US3172114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:50
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User closed query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:02:55
Query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	23 Apr 2021 14:11:34
Signature has been broken.	(b) (4)	
	Mariete Rendon (b) (4)	23 Apr 2021 14:09:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 21:56:37
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Oct 2020 12:02:28
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	Mariete Rendon (b) (4)	12 Oct 2020 19:56:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	12 Oct 2020 19:56:50
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	12 Oct 2020 19:56:50
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	12 Oct 2020 19:56:38
	(b) (4)	

US3172114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:50
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Oct 2020 19:56:38
	(b) (4)	

US3172114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:50
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Oct 2020 19:56:38
	(b) (4)	

US3172114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:50
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Oct 2020 19:56:38
	(b) (4)	

US3172114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:40
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:56:42

US3172114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:40
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 19:56:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:21:32
User entered 'l'	System	12 Oct 2020 19:56:42

US3172114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:57:27

US3172114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '12 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:57:27

US3172114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:57:27

US3172114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'VISIT3'	System	12 Oct 2020 19:57:27

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '12 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '11:04'	Mariete Rendon (b) (4)	12 Oct 2020 19:58:49
	(b) (4)	

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '12 Oct 2020 11:04'	System	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '76'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'bpm'	System	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '13'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'breaths/min'	System	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '129'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '82'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'mmHg'	System	12 Oct 2020 19:58:49

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05

US3172114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05

US3172114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:57

US3172114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:58:57

US3172114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:59:04

US3172114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '12 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:59:04

US3172114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11:24'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:59:04

US3172114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '12 Oct 2020 11:24'	System	12 Oct 2020 19:59:04

US3172114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 19:59:13

US3172114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered '1'	System	12 Nov 2020 20:45:40
User entered empty.	System	12 Oct 2020 19:59:13

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 64'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-15T17:41:51', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cd45d028-6c2a-4a75-bc3d-fa07b655e790'	System	15 Oct 2020 21:42:02
User entered 'No (N)'	System	15 Oct 2020 21:42:02

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Have you been exposed to someone with 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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-15T17:41:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cd45d028-6c2a-4a75-bc3d-fa07b655e790'	System	15 Oct 2020 21:42:02
User entered 'No (N)'	System	15 Oct 2020 21:42:02

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-15T17:41:59', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'cd45d028-6c2a-4a75-bc3d-fa07b655e790'	System	15 Oct 2020 21:42:02
User entered '15 Oct 2020 17:41:59'	System	15 Oct 2020 21:42:02

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 71'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-23T23:24:18', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '97e35ce6-0bbe-4a08-9c4e-35dcfb931bd9'	System	24 Oct 2020 03:24:30
User entered 'No (N)'	System	24 Oct 2020 03:24:30

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-23T23:24:21', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '97e35ce6-0bbe-4a08-9c4e-35dcfb931bd9'	System	24 Oct 2020 03:24:30
User entered 'No (N)'	System	24 Oct 2020 03:24:30

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-10-23T23:24:26', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '97e35ce6-0bbe-4a08-9c4e-35dcfb931bd9'	System	24 Oct 2020 03:24:30
User entered '23 Oct 2020 23:24:26'	System	24 Oct 2020 03:24:30

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 78'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Have you been exposed to someone with 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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Please 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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Please 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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Please 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)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:31:48
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 92'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-11T15:52:11', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '353edc4a-c0a5-41d9-bbbe-2f2097bc9047'	System	11 Nov 2020 20:52:24
User entered 'No (N)'	System	11 Nov 2020 20:52:24

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-11T15:52:14', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '353edc4a-c0a5-41d9-bbbe-2f2097bc9047'	System	11 Nov 2020 20:52:24
User entered 'No (N)'	System	11 Nov 2020 20:52:24

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-11T15:52:19', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '353edc4a-c0a5-41d9-bbbe-2f2097bc9047'	System	11 Nov 2020 20:52:24
User entered '11 Nov 2020 15:52:19'	System	11 Nov 2020 20:52:24

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered 'Day 99'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-18T07:51:41', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '31498de5-b86a-4980-8eba-f77c638ac280'	System	18 Nov 2020 12:51:52
User entered 'No (N)'	System	18 Nov 2020 12:51:52

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-18T07:51:46', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '31498de5-b86a-4980-8eba-f77c638ac280'	System	18 Nov 2020 12:51:52
User entered 'No (N)'	System	18 Nov 2020 12:51:52

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86476b76e70feb52)', Time: '2020-11-18T07:51:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '31498de5-b86a-4980-8eba-f77c638ac280'	System	18 Nov 2020 12:51:52
User entered '18 Nov 2020 07:51:49'	System	18 Nov 2020 12:51:52

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:43:10

US3172114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:09
Data entry locked.	System	14 Aug 2020 17:43:10
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:43:10

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-01-20T14:18:42', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4608a01b-d5b7-409c-b83e-f941e1e963de'	System	20 Jan 2021 19:18:52
User entered 'No (N)'	System	20 Jan 2021 19:18:52

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-01-20T14:18:44', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4608a01b-d5b7-409c-b83e-f941e1e963de'	System	20 Jan 2021 19:18:52
User entered 'No (N)'	System	20 Jan 2021 19:18:52

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-01-20T14:18:48', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '4608a01b-d5b7-409c-b83e-f941e1e963de' User entered '20 Jan 2021 14:18:48'	System	20 Jan 2021 19:18:52

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-01-25T07:15:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ff41809f-51d5-49a2-8b4e-e61644bb7a14'	System	25 Jan 2021 12:15:59
User entered 'No (N)'	System	25 Jan 2021 12:15:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-01-25T07:15:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ff41809f-51d5-49a2-8b4e-e61644bb7a14'	System	25 Jan 2021 12:15:59
User entered 'No (N)'	System	25 Jan 2021 12:15:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-01-25T07:15:56', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ff41809f-51d5-49a2-8b4e-e61644bb7a14' User entered '25 Jan 2021 07:15:56'	System	25 Jan 2021 12:15:59
	System	25 Jan 2021 12:15:59

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-02-01T11:07:45', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7d9b0698-8f50-402c-a3f6-0726704a110f'	System	01 Feb 2021 16:07:55
User entered 'No (N)'	System	01 Feb 2021 16:07:55

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-02-01T11:07:47', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7d9b0698-8f50-402c-a3f6-0726704a110f'	System	01 Feb 2021 16:07:55
User entered 'No (N)'	System	01 Feb 2021 16:07:55

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-01T11:07:51', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '7d9b0698-8f50-402c-a3f6-0726704a110f' User entered '01 Feb 2021 11:07:51'	System	01 Feb 2021 16:07:55
	System	01 Feb 2021 16:07:55

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-02-14T00:34:32', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ec294349-da1e-411b-a303-34452d6cf8f3'	System	14 Feb 2021 05:34:42
User entered 'No (N)'	System	14 Feb 2021 05:34:42

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-02-14T00:34:34', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ec294349-da1e-411b-a303-34452d6cf8f3'	System	14 Feb 2021 05:34:42
User entered 'No (N)'	System	14 Feb 2021 05:34:42

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-14T00:34:37', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'ec294349-da1e-411b-a303-34452d6cf8f3'	System	14 Feb 2021 05:34:42
User entered '14 Feb 2021 00:34:37'	System	14 Feb 2021 05:34:42

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-02-21T00:01:50', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '296355cb-9d04-455f-9ae3-20db25e8eb03'	System	21 Feb 2021 05:02:54
User entered 'No (N)'	System	21 Feb 2021 05:02:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-02-21T00:01:52', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '296355cb-9d04-455f-9ae3-20db25e8eb03'	System	21 Feb 2021 05:02:54
User entered 'No (N)'	System	21 Feb 2021 05:02:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-21T00:01:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '296355cb-9d04-455f-9ae3-20db25e8eb03'	System	21 Feb 2021 05:02:54
User entered '21 Feb 2021 00:01:55'	System	21 Feb 2021 05:02:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (5cd966fd31ee5c53)', Time: '2021-02-28T19:22:47', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '11e92e90-4058-434b-b1f1-a049ae4a4f3a'	System	01 Mar 2021 00:23:00
User entered 'No (N)'	System	01 Mar 2021 00:23:00

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Have you been exposed to someone with 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 (5cd966fd31ee5c53)', Time: '2021-02-28T19:22:49', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '11e92e90-4058-434b-b1f1-a049ae4a4f3a'	System	01 Mar 2021 00:23:00
User entered 'No (N)'	System	01 Mar 2021 00:23:00

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-28T19:22:55', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '11e92e90-4058-434b-b1f1-a049ae4a4f3a'	System	01 Mar 2021 00:23:00
User entered '28 Feb 2021 19:22:55'	System	01 Mar 2021 00:23:00

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-03-09T22:13:24-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '839cc9f3-fda7-45a6-ab82-5d2e06691b30'	System	10 Mar 2021 03:16:18
User entered 'No (N)'	System	10 Mar 2021 03:16:18

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46f6ea9004fc405b)', Time: '2021-03-09T22:13:26-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '839cc9f3-fda7-45a6-ab82-5d2e06691b30'	System	10 Mar 2021 03:16:18
User entered 'No (N)'	System	10 Mar 2021 03:16:18

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-03-09T22:13:29-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '839cc9f3-fda7-45a6-ab82-5d2e06691b30'	System	10 Mar 2021 03:16:18
User entered '09 Mar 2021 22:13:29'	System	10 Mar 2021 03:16:18

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-03-14T08:33:35-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f9d3f4dd-3c9b-4c74-b651-3fbaba4c1943'	System	14 Mar 2021 12:34:05
User entered 'No (N)'	System	14 Mar 2021 12:34:05

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46f6ea9004fc405b)', Time: '2021-03-14T08:33:38-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f9d3f4dd-3c9b-4c74-b651-3fbaba4c1943'	System	14 Mar 2021 12:34:05
User entered 'No (N)'	System	14 Mar 2021 12:34:05

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-03-14T08:33:42-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'f9d3f4dd-3c9b-4c74-b651-3fbaba4c1943' User entered '14 Mar 2021 08:33:42'	System	14 Mar 2021 12:34:05
	System	14 Mar 2021 12:34:05

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-03-28T21:56:18-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'dad23e6e-15a4-400b-b2e7-657f3311f002'	System	29 Mar 2021 01:56:27
User entered 'No (N)'	System	29 Mar 2021 01:56:27

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Have you been exposed to someone with 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 (46f6ea9004fc405b)', Time: '2021-03-28T21:56:20-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'dad23e6e-15a4-400b-b2e7-657f3311f002'	System	29 Mar 2021 01:56:27
User entered 'No (N)'	System	29 Mar 2021 01:56:27

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-03-28T21:56:22-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: 'dad23e6e-15a4-400b-b2e7-657f3311f002' User entered '28 Mar 2021 21:56:22'	System	29 Mar 2021 01:56:27
	System	29 Mar 2021 01:56:27

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-05T08:28:39-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5747e8df-6f41-4e01-8f05-be2b0cea404d' User entered 'No (N)'	System	05 Apr 2021 12:28:54
	System	05 Apr 2021 12:28:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46f6ea9004fc405b)', Time: '2021-04-05T08:28:41-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5747e8df-6f41-4e01-8f05-be2b0cea404d' User entered 'No (N)'	System	05 Apr 2021 12:28:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-04-05T08:28:44-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5747e8df-6f41-4e01-8f05-be2b0cea404d' User entered '05 Apr 2021 08:28:44'	System	05 Apr 2021 12:28:54
	System	05 Apr 2021 12:28:54

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-11T13:46:21-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0486c249-3f37-43c5-99d2-b4da8139a446'	System	11 Apr 2021 17:46:31
User entered 'No (N)'	System	11 Apr 2021 17:46:31

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46f6ea9004fc405b)', Time: '2021-04-11T13:46:23-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0486c249-3f37-43c5-99d2-b4da8139a446'	System	11 Apr 2021 17:46:31
User entered 'No (N)'	System	11 Apr 2021 17:46:31

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-04-11T13:46:25-04:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '0486c249-3f37-43c5-99d2-b4da8139a446'	System	11 Apr 2021 17:46:31
User entered '11 Apr 2021 13:46:25'	System	11 Apr 2021 17:46:31

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-18T11:15:25-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered 'Yes (Y)'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46feea9004fc405b)', Time: '2021-04-18T11:15:27-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered 'Yes (Y)'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Please 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 (46feea9004fc405b)', Time: '2021-04-18T11:15:45-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-18T11:15:52-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered 'No (N)'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46f6ea9004fc405b)', Time: '2021-04-18T11:16:00-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered 'No (N)'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-04-18T11:16:03-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '2f4bebdba-be00-44cf-9d7c-05799df29f82'	System	18 Apr 2021 16:16:14
User entered '18 Apr 2021 11:16:03'	System	18 Apr 2021 16:16:14

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-26T08:17:20-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340' User entered 'Yes (Y)'	System	26 Apr 2021 13:18:06
	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Have you been exposed to someone with 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 (46feea9004fc405b)', Time: '2021-04-26T08:17:38-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340' User entered 'Yes (Y)'	System	26 Apr 2021 13:18:06
	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

Please 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 (46feea9004fc405b)', Time: '2021-04-26T08:17:41-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340'	System	26 Apr 2021 13:18:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-26T08:17:46-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340' User entered 'No (N)'	System	26 Apr 2021 13:18:06
	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[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 (46feea9004fc405b)', Time: '2021-04-26T08:17:52-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340'	System	26 Apr 2021 13:18:06
User entered 'No (N)'	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46feea9004fc405b)', Time: '2021-04-26T08:17:54-05:00', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '3dead901-1d9f-471c-861a-ac1959727340' User entered '26 Apr 2021 08:17:54'	System	26 Apr 2021 13:18:06
	System	26 Apr 2021 13:18:06

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:31:48

US3172114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:31:48
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:31:48

US3172114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:05

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-27T18:09:51', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5b13110b-68bb-4abe-bdcb-1318c6c31a6f'	System	27 Feb 2021 23:12:11
User entered 'No (N)'	System	27 Feb 2021 23:12:11

US3172114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cd966fd31ee5c53)', Time: '2021-02-27T18:09:58', User OID: 'PatientReportedOutcome (US3172114)', ODM File OID: '5b13110b-68bb-4abe-bdcb-1318c6c31a6f'	System	27 Feb 2021 23:12:11
User entered '27 Feb 2021 18:09:58'	System	27 Feb 2021 23:12:11

US3172114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:53

US3172114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Nov 2020'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:53

US3172114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:53

US3172114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:53

US3172114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:45:57

US3172114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:22:05
User entered 'I'	System	12 Nov 2020 20:45:57

US3172114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:58

US3172114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:58

US3172114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:58

US3172114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:58

US3172114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:58:20

US3172114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User entered 'I'	System	14 Dec 2020 20:58:20

US3172114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:57:36

US3172114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	17 Feb 2021 10:16:10
	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Participant Decision Visit / OL-D1 was added to EDC.' (Site from DM).	Jessie Downs (b) (4)	11 Feb 2021 17:14:18
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:52:10
User entered '14 Jan 2021'	Jessie Downs (b) (4)	01 Feb 2021 20:57:36
	(b) (4)	

US3172114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:57:36

US3172114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	01 Feb 2021 20:57:36
	(b) (4)	

US3172114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:40:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:40:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:58:01
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:57:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 20:57:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:57:45
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:57:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:57:42

US3172114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User entered 'I'	System	16 Mar 2021 18:40:27
User entered empty.	System	01 Feb 2021 20:58:01
User entered 'I'	System	01 Feb 2021 20:57:45
User entered empty.	System	01 Feb 2021 20:57:42

US3172114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:40:46

US3172114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:27
User entered 'I'	System	16 Mar 2021 18:40:46

US3172114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:41:00

US3172114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '16 Mar 2021'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:41:00

US3172114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[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 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:41:00

US3172114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'VISIT4'	System	16 Mar 2021 18:41:00

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '16 Mar 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '12:24'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '16 Mar 2021 12:24'	System	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '97'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'bpm'	System	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '17'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'breaths/min'	System	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '160'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'mmHg'	System	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:18:15
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'As per sub I diastolic blood pressure was deemed abnormal NCS.' (Site from System).	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:12
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Apr 2021 19:30:56
User entered '104'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'mmHg'	System	15 Apr 2021 19:30:56

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10

US3172114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10

US3172114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:45:43

US3172114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:45:43

US3172114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:45:59

US3172114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '16 Mar 2021'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:45:59

US3172114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '13:52'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:45:59

US3172114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered '16 Mar 2021 13:52'	System	16 Mar 2021 18:45:59

US3172114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:46:03

US3172114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:17:10
User entered 'I'	System	16 Mar 2021 18:46:03

US3172114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:32

US3172114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered '14 Apr 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:32

US3172114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:32

US3172114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:32

US3172114

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:33:36

US3172114

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:33:36

US3172114

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

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:34:47

US3172114

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

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:34:47

US3172114

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

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:34:47

US3172114

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

Form: Visit Date

Generated On: 09 Jun 2021 15:37:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 16:34:47

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:10:48
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:48:29

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:34:34
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:13:35
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:13:14
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:13:14
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 21:01:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:10:48
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:48:29

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '29 Jan 2021'	Jessie Downs (b) (4)	10 Feb 2021 16:35:53
	(b) (4)	

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User entered empty.	System	10 Feb 2021 16:35:53

US3172114

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

Form: Unblinding

Generated On: 09 Jun 2021 15:37:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User entered empty.	System	10 Feb 2021 16:35:53

US3172114

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:16

US3172114

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:16

US3172114

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '10:30'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:16

US3172114

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User entered '29 Jan 2021 10:30'	System	10 Feb 2021 16:35:16

US3172114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:29

US3172114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:29

US3172114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '10:31'	Jessie Downs (b) (4) (b) (4)	10 Feb 2021 16:35:29

US3172114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:49
User entered '29 Jan 2021 10:31'	System	10 Feb 2021 16:35:29

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:37:05

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:59:08

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:37:05

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:59:08

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:37:05

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:59:08

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:37:05

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:59:08

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:37:05

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:59:08

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14:06'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User entered '14 Dec 2020 14:06'	System	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '103'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User entered 'bpm'	System	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '16'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User entered 'breaths/min'	System	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '143'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User entered 'mmHg'	System	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '87'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30
User entered 'mmHg'	System	14 Dec 2020 21:00:03

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:30

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:35
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:14

US3172114

Folder: Unscheduled 14 Dec 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:35
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 21:00:14

US3172114

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:37:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 19:43:25
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:07:05

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:00:29
User entered 'USA-US118-2020-mRNA-1273-P301000013'	System	15 Dec 2020 15:00:21
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 15:00:21

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Could you clarify if "collapse" refers to an actual fall or if it refers to circulatory collapse? As such, please consider separating into separate events. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:40:41
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:27:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:27:42
Data point term sent to Coder	System	09 Apr 2021 19:29:30
DataPoint Un-verified.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:29:02
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:29:02
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:29:02
User entered 'SYNCOPE and collapse (primary)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:29:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:35
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:13:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:13:47
Data point term sent to Coder	System	14 Dec 2020 20:12:59
User entered 'SYNCOPE'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Answer still says no. Please change and save.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:19:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:01
Query 'Answer still says no. Please change and save.' answered by data change (Site from CRA).	System	14 Apr 2021 14:04:42
Signature has been broken.	Jessie Downs (b) (4)	14 Apr 2021 14:04:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Apr 2021 14:04:42
User opened query 'Answer still says no. Please change and save.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:25:33
User closed query 'Per Unscheduled Visit source documents, subject was hospitalized; therefore, this was a medically attended AE. If correct, please review and update to yes both on the SAE source worksheet and here.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:25:33
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 22:40:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 22:40:11
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 22:40:11
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 22:39:48
Query 'Per Unscheduled Visit source documents, subject was hospitalized; therefore, this was a medically attended AE. If correct, please review and update to yes both on the SAE source worksheet and here.' answered by data change (Site from CRA).	System	26 Feb 2021 22:39:48
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 22:39:48
User opened query 'Per Unscheduled Visit source documents, subject was hospitalized; therefore, this was a medically attended AE. If correct, please review and update to yes both on the SAE source worksheet and here.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 19:11:33
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:41
User entered '15 Nov 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:43
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	14 Dec 2020 20:13:22
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:13:22
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Dec 2020 20:12:55
User entered '17:00'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:13:22
User entered '15 Nov 2020 17:00'	System	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:45
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:32
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:26
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:29:02
User entered '17 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:29:02
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:51
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:47
User closed query 'Per DM CLR: Please review and verify the stop date of this AE as this is not expected to last for more than 1 day. Update eCRF as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:42:53
Query 'Per DM CLR: Please review and verify the stop date of this AE as this is not expected to last for more than 1 day. Update eCRF as appropriate. Otherwise, clarify. answered with 'Date verified. Data correct as entered.' (Site from DM).	Jessie Downs (b) (4)	15 Jan 2021 14:44:37
User opened query 'Per DM CLR: Please review and verify the stop date of this AE as this is not expected to last for more than 1 day. Update eCRF as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:36:07
User entered '18 Nov 2020'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:55
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Dec 2020 20:13:22
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:13:22
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Dec 2020 20:12:55
User entered '14:00'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:13:22
User entered '18 Nov 2020 14:00'	System	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:11:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:00
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:57:43
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:12:55
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:03
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:05
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		14 Dec 2020 20:57:43
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		14 Dec 2020 20:57:43
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:57:43
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	14 Dec 2020 20:57:29
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:07
User entered '15 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:57:29
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:17
User closed query 'Per unscheduled visit source documents, hospitalized until 18 Nov, however, per SAE source worksheet, discharged 15 Nov. Please consolidate and update as needed.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:21:10
User closed query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 13:15:37
Query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field. ' answered with 'Subject was discharged 17NOV2020.' (Site from Safety).	Jessie Downs (b) (4)	14 Apr 2021 14:00:59
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:29:02
User entered '17 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:29:02
User opened query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:52:50
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 22:40:51
User entered '15 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 22:40:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 22:39:48
Query 'Per unscheduled visit source documents, hospitalized until 18 Nov, however, per SAE source worksheet, discharged 15 Nov. Please consolidate and update as needed.' answered by data change (Site from CRA).	System	26 Feb 2021 22:39:48
User entered '15 2020' (non-conformant).	Jessie Downs (b) (4)	26 Feb 2021 22:39:48

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per unscheduled visit source documents, hospitalized until 18 Nov, however, per SAE source worksheet, discharged 15 Nov. Please consolidate and update as needed.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 19:14:32
User entered '15 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:57:29
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:13
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:16
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:18
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:22
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:23
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:12:30
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:39
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:44:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 20:44:34
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:01:09
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:43:03
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Pending to receive medical records.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 14:45:52
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:36:22
User entered 'I'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:30
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:31
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:33
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:36
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:12:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: -Please confirm if severe pansinusitis seen on MRI (07-Dec-2020) could be the cause behind the syncopal episodes.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:00:59
User closed query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:22:04
Query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' answered with 'Data updated in narrative, however, x-ray findings could not be completed due to no more space.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 20:43:09

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT RETURNED THIS AFTERNOON AFTER BEING HERE TO DROP DISCHARGE INSTRUCTIONS FOR ADM FROM 4DEC-11DEC AND DURING UNSCH VISIT HE DISCLOSED HAD ANOTHER ADMISSION ON 15NOV-18NOV. AT THE SAME UM HOSPITAL THAT HE WENT DUE TO TRANSIENT LOOSENING OF CONSCIENCE THEN AND NOW ON 4DEC. HE DIDN'T HAVE ANY PARALYSIS, MUSCLE WEAKNESS OR OTHER MOTOR OR SENSORIAL SYMPTOMS. PENDING MEDICAL RECORDS FOR BOTH ADM. TODAY HE IS ASYMPTOMATIC WITH NO SEQUELS OBSERVED WITH A NORMAL PHYSICAL EXAM INCLUDING NEUROLOGIC. COVID 19 ACCULA RNA NAAT 15NOV2020 NOT DETECTED. 15NOV2020 TROPONIN T <0.01 REF RANGE: 0.00-0.06 NG/ML. EKG REPORT 15NOV2020 RESULT: NORMAL SINUS RHYTHM, NONSPECIFIC T WAVE ABNORMALITY, ABNORMAL ECG, WHEN COMPARED WITH ECG OF 01NOV2020, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN INFERIOR LEADS, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN LATERAL LEADS. ECHO 2D DOPPLER-COLOR FLOW 16NOV2020 INTERPRETATION: THERE IS MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY, LEFT VENTRICULAR SYSTOLIC FUNCTION IS NORMAL, EJECTION FRACTION= 60-65%, GRADE I DIASTOLIC DYSFUNCTION, (ABNORMAL RELAXATION PATTERN), RIGHT VENTRICULAR SYSTOLIC PRESSURE IS NORMAL, THERE IS NO PERICARDIAL EFFUSION. CT HEAD WITHOUT CONTRAST 15NOV2020 FINDINGS: THERE IS ADVANCED PARANASAL SINUS DISEASE WITH MUCOSAL THICKENING AND OPACIFICATION FRONTAL SINUSES ARE NEARLY COMPLETELY OPACIFIED WITH SMALL LEFT FRONTAL SINUS FLUID LEVEL	Mariete Rendon (b) (4)	22 Apr 2021 20:42:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

1724 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
SUGGESTED. RIGHT MAXILLARY SINUS FLUID LEVEL ALSO SUGGESTED. THE MASTOID AIR CELLS ARE WITHOUT SUBSTANTIAL ABNORMALITY. NO SUSPICIOUS CALVARIAL LESIONS. ACUTE ON CHRONIC WIDESPREAD PARANASAL SINUSITIS. CHEST XRAY AP ONLY 15NOV2020 FINDINGS: THERE IS NORMAL CARDIOMEDIASTINAL CONTOUR. THE LUNGS ARE WELL EXPANDED AND APPEAR CLEAR WITH THE EXCEPTION OF SWOME PERSISTENT SMALL CLUSTERED NODULAR OPACITIES PROJECTING OVER THE LATERAL ASPECT OF THE LEFT MIDLUNG, BUT CANNOT EXCLUDE THAT THIS IS WITHIN THE OVERLYING RIB. NO PLEURAL EFFUSION. NO PNEUMOTHORAX. xray FINDING NOT COMPLETED NO MORE SPACE.' reason for change: Data Entry Error		

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT RETURNED THIS AFTERNOON AFTER BEING HERE to DROP DISCHARGE INSTRUCTIONS FOR ADM FROM 4DEC-11DEC AND DURING UNSCH VISIT HE DISCLOSED HAD ANOTHER ADMISSION on 15NOV-18NOV. at THE SAME UM HOSPital THAT HE WENT DUE TO TRANSIENT LOOSENING OF CONSCIENCE THEN AND NOW ON 4DEC. HE DIDN'T HAVE ANY PARALYSIS, MUSCLE WEAKNESS OR OTHER MOTOR OR SENSORIAL SYMPTOMS. PENDING mEDICAL RECORDS FOR BOTH ADM. TODAY HE IS ASYMPTOMATIC WITH NO SEQUELS OBSERVED WITH A NORMAL PHYSICAL EXAM INCLUDING NEUROLOGIC. COVID 19 ACCULA RNA NAAT 15NOV2020 NOT DETECTED. 15NOV2020 TROPONIN T <0.01 REF RANGE: 0.00-0.06 NG/ML. EKG REPORT 15NOV2020 RESULT: NORMAL SINUS RHYTHM, NONSPECIFIC T WAVE ABNORMALITY, ABNORMAL ECG, WHEN COMPARED WITH ECG OF 01NOV2020, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN INFERIOR LEADS, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN LATERAL LEADS. ECHO 2D DOPPLER-COLOR FLOW 16NOV2020 INTERPRETATION: THERE IS MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY, LEFT VENTRICULAR SYSTOLIC FUNCTION IS NORMAL, EJECTION FRACTION= 60-65%, GRADE I DIASTOLIC DYSFUNCTION, (ABNORMAL RELAXATION PATTERN), RIGHT VENTRICULAR SYSTOLIC PRESSURE IS NORMAL, THERE IS NO PERICARDIAL EFFUSION. CT HEAD WITHOUT CONTRAST 15NOV2020 FINDINGS: THERE IS ADVANCED PARANASAL SINUS DISEASE WITH MUCOSAL THICKENING AND OPACIFICATION FRONTAL SINUSES ARE NEARLY COMPLETELY OPACIFIED WITH SMALL LEFT FRONTAL SINUS FLUID LEVEL	Mariete Rendon (b) (4)	22 Apr 2021 20:41:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

1726 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
SUGGESTED. RIGHT MAXILLARY SINUS FLUID LEVEL ALSO SUGGESTED. THE MASTOID AIR CELLS ARE WITHOUT SUBSTANTIAL ABNORMALITY. NO SUSPICIOUS CALVARIAL LESIONS. ACUTE ON CHRONIC WIDESPREAD PARANASAL SINUSITIS. Chest Xray AP only 15NOV2020 Findings: There is normal cardiomedial contour. The lungs are well expanded and appear clear with the exception of some persistent small clustered nodular opacities projecting over the lateral aspect of the left midlung, but cannot exclude that this is within the overlying rib. No pleural effusion. No pneumothorax. Echo finding not completed no more space.' reason for change: Data Entry Error Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 20:28:36

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT RETURNED THIS AFTERNOON AFTER BEING HERE DROPPING DISCHARGE INSTRUCTIONS FOR ADMISSION FROM DECEMBER 4 TO DECEMBER 11 AND DURING UNSCHEDULED VISIT HE DISCLOSED HAD ANOTHER ADMISSION FROM NOVEMBER 15 TO NOVEMBER 18. IT IS THE SAME UM HOSPITAL THAT HE WENT BY HIMSELF DUE TO TRANSIENT LOOSENING OF CONSCIENCE THEN AND NOE ON DECEMBER 4 WHEN HE DIDNT HAVE ANY PARALYSIS, MUSCLE WEAKNESS OR OTHER MOTOR OR SENSORIAL SYMPTOMS. PENDING TO RETRIEVE MEDICAL RECORDS FOR BOTH ADMISSIONS. TODAY HE IS ASYMPTOMATIC WITH NO SEQUELS OBSERVED WITH A NORMAL PHYSICAL EXAM INCLUDING NEUROLOGIC. COVID 19 ACCULA RNA NAAT 15NOV2020 NOT DETECTED. 15NOV2020 troponin T <0.01 REF RANGE: 0.00-0.06 ng/ml. EKG REPORT 15NOV2020 Result: Normal sinus rhythm, nonspecific, t wave abnormality, Abnormal ECG, When compared with ECG of 01NOV2020, nonspecific t wave abnormality now evident in inferior leads, nonspecific t wave abnormality now evident in lateral leads. Echocardiogram 2d doppler-color flow 16NOV2020 Interpretation: There is mild concentric left ventricular hypertrophy, left ventricular systolic function is normal, ejection fraction= 60-65%, Grade I diastolic dysfunction, (abnormal relaxation pattern), Right ventricular systolic pressure is normal, there is no pericardial effusion. CT head without contrast 15NOV2020 Findings: There is advanced paranasal sinus disease with mucosal thickening and opacification frontal sinuses are nearly completely opacified with small left frontal sinus fluid level suggested. Right maxillary sinus fluid level also suggested. The mastoid air cells are without substantial abnormality. No suspicious calvarial lesions. acute on chronic widespread paranasal sinusitis.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 20:28:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

1728 of 2608

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:40:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	(b) (4), (b) (6)	15 Apr 2021 13:15:58
' (Site from Safety).		
User closed query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 13:15:55
User closed query 'PV Query: Kindly confirm if any cause of syncope was determined . If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 13:15:51
User closed query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 13:15:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 14:04:14
' answered with 'Concomitant medication related to 15NOV2020 - 17NOV2020 were recorded in the concomitant medication log. ' (Site from Safety).		
Query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' answered with 'EKG, Echo and Brilin CT scan ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 14:02:58

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' answered with 'No CVA was replaced by syncope into collapse.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 14:02:13
Query 'PV Query: Kindly confirm if any cause of syncope was determined . If yes, kindly provide diagnosis ' answered with 'Likely due to dehydration.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 14:01:31
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	(b) (4), (b) (6)	09 Apr 2021 12:54:06
' (Site from Safety).		
User opened query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:53:37
User opened query 'PV Query: Kindly confirm if any cause of syncope was determined . If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:53:08
User opened query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:53:00
User closed query 'PV Query: Kindly confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:49:40
User closed query ' . PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:49:34

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:49:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
User closed query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:12:56
User closed query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:12:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:39:18
Query '. PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:39:04
Query 'PV Query: Kindly confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:38:50
Query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:38:37

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:38:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:42:31
User opened query ' . PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:42:19
User opened query 'PV Query: Kindly confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:42:02
Query 'PV Query: Kindy confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:41:50
User opened query 'PV Query: Kindy confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:41:42
User opened query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:41:30
User opened query 'PV Query: Please confirm discharge date was 18 Nov 2020 (as provided in narrative). If yes, please update hospital discharge date field.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:41:18
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:36

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:34
User closed query 'PV Query: Kindly confirm if any cause of syncope was determined . If yes, kindly provide diagnosis' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:32
User closed query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:30
User closed query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:55:29
Query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:47:08
Query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020.' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:47:03
Query 'PV Query: Kindly confirm if any cause of syncope was determined . If yes, kindly provide diagnosis' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:46:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:46:52

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:44:57
User opened query 'PV query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:58:51
User opened query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:58:27
User opened query 'PV Query: Kindy confirm if any cause of syncope was determined . If yes, kindly provide diagnosis' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:57:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:57:19
User closed query 'PV Query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:19
User closed query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:17
User closed query ' . PV Query: Kindy confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:15
User closed query ' . PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:13

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:48:18
Query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:47:52
Query '. PV Query: Kindy confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:46:48
Query '. PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:46:24
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:03:06
User opened query 'PV Query: Kindly confirm if any diagnostic test was performed (Echo, Holter, stress etc.) and kindly provide the result' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:02:51
User opened query 'PV Query: Please confirm or clarify whether the event "syncope" was the first neurological manifestation of the CVA diagnosed on 04 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:02:27
User opened query '. PV Query: Kindy confirm if any cause of syncope was determined. If yes, kindly provide diagnosis ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:02:04

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query '. PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 12:01:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:57:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 20:57:29
User entered 'SUBJECT RETURNED THIS AFTERNOON AFTER BEING HERE DROPPING DISCHARGE INSTRUCTIONS FOR ADMISSION FROM DECEMBER 4 TO DECEMBER 11 AND DURING UNSCHEDULED VISIT HE DISCLOSED HAD ANOTHER ADMISSION FROM NOVEMBER 15 TO NOVEMBER 18. IT IS THE SAME UM HOSPITAL THAT HE WENT BY HIMSELF DUE TO TRANSIENT LOOSENING OF CONSCIENCE THEN AND NOE ON DECEMBER 4 WHEN HE DIDNT HAVE ANY PARALYSIS, MUSCLE WEAKNESS OR OTHER MOTOR OR SENSORIAL SYMPTOMS. PENDING TO RETRIEVE MEDICAL RECORDS FOR BOTH ADMISSIONS. TODAY HE IS ASYMPTOMATIC WITH NO SEQUELS OBSERVED WITH A NORMAL PHYSICAL EXAM INCLUDING NEUROLOGIC.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:57:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:12:55
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 14:04:42
User entered '0'	System	14 Dec 2020 20:12:55

US3172114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 20:57:29

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:16:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:41
User entered 'USA-US118-2020-mRNA-1273-P301000014'	System	15 Dec 2020 15:01:35
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 15:01:35

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 21:02:19
User opened query 'PV Query: As the subject previously experienced syncope and collapse on 15 Nov 2020, Was this SAE (syncope) considered a worsening of the subject's medical history? If so, please consider updating event term to include disease progression. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:13:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:50
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 19:32:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Apr 2021 19:32:45
Data point term sent to Coder	System	09 Apr 2021 19:31:36
DataPoint Un-verified.	Mariete Rendon (b) (4)	09 Apr 2021 19:31:03
Coding entries removed.	(b) (4)	09 Apr 2021 19:31:03
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:31:03
User entered 'syncope' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 19:31:03
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4)	18 Feb 2021 19:16:04
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:17:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Dec 2020 20:17:41
Data point term sent to Coder	System	14 Dec 2020 20:17:00
User entered 'CEREBROVASCULAR ACCIDENT'	Jessie Downs (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Mariete Rendon (b) (4)	22 Apr 2021 15:47:20
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 15:47:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 15:47:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:26:48
	(b) (4), (b) (6)	
User closed query 'Per source, subject was seen in the hospital, therefore, it was medically attended AE. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:26:45
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
Query 'Per source, subject was seen in the hospital, therefore, it was medically attended AE. Please verify and update as needed.' answered by data change (Site from CRA).	System	26 Feb 2021 22:41:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 22:41:25
	(b) (4)	
User opened query 'Per source, subject was seen in the hospital, therefore, it was medically attended AE. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 19:16:46
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:16:20
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:16:56
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:16:58
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:00
User entered '04 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:02
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	14 Dec 2020 20:16:37
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:37
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	14 Dec 2020 20:16:20
User entered '15:00'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:16:37
User entered '04 Dec 2020 15:00'	System	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:03
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:05
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:07
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Dec 2020 20:16:37
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Dec 2020 20:16:20
User entered '09:30'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:16:37
User entered '11 Dec 2020 09:30'	System	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:10
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:46:29
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:16:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:29
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:31
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	14 Dec 2020 20:50:44
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).		14 Dec 2020 20:50:44
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	14 Dec 2020 20:46:29
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:46:29
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:16:20
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:33
User entered '04 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:50:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:34
User entered '11 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:50:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:37
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:50:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:43
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:46
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:48
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:49
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4)	01 Feb 2021 20:43:49
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:17:51
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Note that there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Ensure that AE term and CM indication are verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:43:41
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Note that there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Ensure that AE term and CM indication are verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Concomitant Medication is recorded with all medications taken.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 13:57:02
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Note that there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Ensure that AE term and CM indication are verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:21:32
User closed query 'Per DM CLR: RQ: Response noted, however, there is still no treatment recorded in the CM eCRF. Please review and record the treatment as appropriate. Note: please don't close the query until treatment is recorded.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:13:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
Query 'Per DM CLR: RQ: Response noted, however, there is still no treatment recorded in the CM eCRF. Please review and record the treatment as appropriate. Note: please don't close the query until treatment is recorded.' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:41:41

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, there is still no treatment recorded in the CM eCRF. Please review and record the treatment as appropriate. Note: please don't close the query until treatment is recorded.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 05:24:10
	(b) (4), (b) (6)	18 Feb 2021 19:18:03
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:43:21
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 14:49:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:36:48
User entered 'I'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:18:05
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:18:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:18:08
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the subject previously experienced syncope and collapse on 15 Nov 2020, please consider adding it to medical history in EDC. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:13:25
User opened query 'PV Query: Please send a hospital discharge summary for the hospitalization for 04 Dec 2020 through 11 Dec 2020 and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:12:09
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:11:57
User closed query 'PV query: Please provide the dates and results for the reported carotid ultrasound, MRI, electrocardiogram, and drug screen.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 11:27:38
Query 'PV query: Please provide the dates and results for the reported carotid ultrasound, MRI, electrocardiogram, and drug screen.' answered with 'Data entered in narrative.' (Site from Safety).	Mariete Rendon (b) (4)	22 Apr 2021 20:07:38
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 20:01:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT SEEN COMING WALKING BY HIMSELF TO SITE THIS MORNING. JUST LEFT DISCHARGE INSTRUCTIONS WITH COORDINATOR SAYING HE WAS ADMITTED TO UNIVERSITY OF MIAMI HOSPITAL AND COULDN'T WAIT TO SEE AN INVESTIGATOR. SUBJECT CALLED TO EMERGENCY CONTACT. HE IS PROVIDING us HIS PRIMARY PHONE NUMBER AND SPOKE WITH EMERGENCY CONTACT WHO SAID HE IS NOT THERE AT THIS TIME. MEDICAL RECORDS TO BE REQUESTED. carotid ultrasound 05DEC2020 Impression: No hemodynamically significant lesions int he rica (less than 59% stenosis). Color duplex ultrasound evaluation demonstrates a patent carotid system with minimal spectral broadening. MRI 07dec2020 Impression: 1. severe pansinusitis and right mastoid disease. secretions demonstrated low t2 signal centrally which could be an indication of chronic inspissation versus fungal colonization of secretions. 2.aging brain with signs of preventricular and juxtacortical ischemic leukomalacia as well as small old lacunar infarctions in bilateral peritigonal white matter regions. 3.no signs of focal brain masses, mass effect, hydrocephalus or abnormal extra-axial collections. No abnormal intracranial enhancement. The brain diffusion is normal. 4. Brain MRA showing no areas of vascular critical stenosis or aneurysm measuring over 0.25cm in the intracranial supra or infratentorial arterial vasculature visualized. COVID 19 Accula RNA NAAT 04DEC2020 not detected. 04DEC2021 Hemoglobin 10.9L Ref range: 13.3-16.3 g/dl and Hematocrit 33.0L Ref range: 39.0-47.1%. EKG report 04DEC2020 Inverted T waves in inferior leads II, III, aVF and lateral leads V5 V6. abnormal EKG without evidence of STEMI. Negative troponin. Toxicology screen 07DEC2020 Cocaine metabolites, Urine- Result: Positive.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 20:01:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the dates and results for the reported carotid ultrasound, MRI, electrocardiogram, and drug screen.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:22:44
User closed query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 12:53:59
User closed query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 12:53:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:09:55
Query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available. Please leave query open until information is received. ' answered with 'No CVA an adverse event.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 12:17:43
Query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available. Please leave query open until information is received. ' answered with 'Carotid US report, MRI report, EKG report and positive drug screen.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 13:59:51

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received. ' answered with 'No specific treatment other than concomitant medications taken.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	14 Apr 2021 13:58:24
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:46:35
User opened query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:46:26
User opened query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:46:20
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:46:07

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:50:06
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:15:29
User closed query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:15:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:42:23
	(b) (4)	
Query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:42:08
	(b) (4)	
Query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:41:55
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:46:38
User opened query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:46:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:57:13
User closed query 'PV Query: Please consider updating the action taken with study drug to not applicable. As per source, subject received both doses of study drug.	(b) (4), (b) (6)	02 Feb 2021 13:57:08
' (Site from Safety).		
User closed query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:57:07
Query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:46:21

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No medical records received. Pending.' (Site from Safety).	Jessie Downs (b) (4)	01 Feb 2021 20:46:16
Query 'PV Query: Please consider updating the action taken with study drug to not applicable. As per source, subject received both doses of study drug.	Jessie Downs (b) (4)	01 Feb 2021 20:44:05
' answered with 'Data was updated.' (Site from Safety).		
User opened query 'PV Query: Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:37:22
User opened query 'PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:36:59
User closed query 'Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. ' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:34
User closed query ' . PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:11:32
Query 'Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. ' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:50:01
Query ' . PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	15 Jan 2021 14:49:24

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the action taken with study drug to not applicable. As per source, subject received both doses of study drug. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:22:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:21:56
User opened query 'Please confirm or clarify if this event of cerebrovascular accident is related to the subject's previously reported event of syncope. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:21:33
User opened query '. PV Query: Kindly confirm if any diagnostic test was performed and provide results if applicable. E.g. MRI, CT OR MR angiogram, EEG, ECG OR EKG etc' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:21:13
User entered 'SUBJECT SEEN COMING WALKING BY HIMSELF TO SITE THIS MORNING. JUST LEFT DISCHARGE INSTRUCTIONS WITH COORDINATOR SAYING HE WAS ADMITTED TO UNIVERSITY OF MIAMI HOSPITAL AND COULDN'T WAIT TO SEE AN INVESTIGATOR. SUBJECT CALLED TO EMERGENCY CONTACT. HE IS PROVIDING AS HIS PRIMARY PHONE NUMBER AND SPOKE WITH EMERGENCY CONTACT WHO SAID HE IS NOT THERE AT THIS TIME. MEDICAL RECORDS TO BE REQUESTED.'	Jessie Downs (b) (4)	14 Dec 2020 20:50:44
reason for change: Data Entry Error		
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:46:06
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 20:46:06

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT SEEN COMING WALKING BY HIMSELF TO SITE THIS MORNING. JUST LEFT DISCHARGE INSTRUCTIONS WITH COORDINATOR SAYING HE WAS ADMITTED TO UNIVERSITY OF MIAMI HOSPITAL AND COULDNT WAIT TO SEE AN INVESTIGATOR. SUBJECT CALLED TO EMERGENCY CONTACT.' reason for change: Data Entry Error	Jessie Downs (b) (4)	14 Dec 2020 20:46:06
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:16:20
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 15:47:20
User entered '1'	System	26 Feb 2021 22:41:25
User entered '0'	System	14 Dec 2020 20:16:20

US3172114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 20:50:44

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:29:55
User entered 'USA-US118-2020-mRNA-1273-P301000013'	(b) (4), (b) (6)	12 Apr 2021 20:29:41

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 19:39:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 19:39:46
Data point term sent to Coder	System	09 Apr 2021 19:37:46
Coding entries removed.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
Signature has been broken.	(b) (4)	
	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User entered 'Acute Kidney Injury' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
User signature succeeded.	(b) (4)	
	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User closed query 'Per DM CLR: Please confirm the AE term "COPD EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:37:37
Query 'Per DM CLR: Please confirm the AE term "COPD EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' answered with 'Data was updated in medical history.' (Site from DM).	Jessie Downs (b) (4)	01 Feb 2021 15:59:23
	(b) (4)	
User opened query 'Per DM CLR: Please confirm the AE term "COPD EXACERBATION", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:37:53

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 19:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 19:24:40
Data point term sent to Coder	System	23 Dec 2020 19:24:01
User entered 'copd exacerbation'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify the dates for the event acute kidney injury. as medical records suggest event onset and hospitalization dates as 04 Dec 2020 -11 Dec 2020. please reconcile.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:01:31
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '23 Dec 2020'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
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	23 Dec 2020 19:23:12
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:23:12
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Dec 2020 19:23:05
User entered '08:00'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 19:23:12
User entered '23 Dec 2020 08:00'	System	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:17
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User entered '17 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '28 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:17
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Dec 2020 22:43:26
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:26
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Dec 2020 22:43:17
User entered '08:01' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:17
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 22:43:26
User entered '28 Dec 2020 08:01'	System	29 Dec 2020 22:43:17
User entered empty.	System	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 19:51:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 19:51:20
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:51:20
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:37:41
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:41:24
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:16:10
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Apr 2021 19:54:14
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:59:20
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:59:12
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:57:40
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Apr 2021 19:37:41
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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	12 Apr 2021 20:15:55
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).	System	12 Apr 2021 20:15:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Apr 2021 19:54:14
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Apr 2021 19:54:14
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	12 Apr 2021 19:54:14
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:54:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:54:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Apr 2021 19:51:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify dates of hospitalization (04 Dec 2020- 11 Dec 2020) for event acute kidney injury; event stated to have started on 15 Nov 2020 and ended 17 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:22:35
Query 'PV Query: Please clarify dates of hospitalization (04 Dec 2020- 11 Dec 2020) for event acute kidney injury; event stated to have started on 15 Nov 2020 and ended 17 Nov 2020. ' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4)	22 Apr 2021 16:54:48
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 16:54:40
User opened query 'PV Query: Please clarify dates of hospitalization (04 Dec 2020- 11 Dec 2020) for event acute kidney injury; event stated to have started on 15 Nov 2020 and ended 17 Nov 2020. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:40:04
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:51:20
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:51:20
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 16:54:40
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:51:20
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:51:20
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:15:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:15:55
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Signature has been broken.	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4)	09 Apr 2021 19:37:41
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'None (NONE)'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). Signature has been broken.	System (b) (4), (b) (6)	12 Apr 2021 20:15:55 12 Apr 2021 20:15:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:15:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User signature succeeded.	System Mark Kutner (b) (4) (b) (4)	09 Apr 2021 19:37:41 03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:37:41
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:37:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:37:48
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'Subject suffers from COPD. Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 16:00:19
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:38:04
User entered '1'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:17
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4)	23 Dec 2020 19:23:05
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:37:01
User closed query 'PV Query: Please provide units and reference ranges for creatinine and GFR levels if possible.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:36:57
Query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' answered with 'Data updated in narrative.' (Site from Safety).	Mariete Rendon (b) (4)	23 Apr 2021 13:59:47
Query 'PV Query: Please provide units and reference ranges for creatinine and GFR levels if possible.' answered with 'Data updated in narrative.' (Site from Safety).	Mariete Rendon (b) (4)	23 Apr 2021 13:59:44

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 1.65 REF RANGE: 0.4-1.1 MG/DL AND GFR 51 >59 ML/MIN/1.73M2. CONSISTENT WITH ACUTE KIDNEY FAILURE SECONDARY TO DEHYDRATION THAT RESOLVED BY 17NOV WITH CREATININE LEVELS OF 1.19 REF RANGE: 0.4-1.1 MG/DL AND GFR IN 75 REF RANGE: >59 ML/MIN/1.73M2. COVID 19 ACCULA RNA NAAT 15NOV2020 NOT DETECTED. EKG REPORT 15NOV2020 RESULT: NORMAL SINUS RHYTHM, NONSPECIFIC T WAVE ABNORMALITY, ABNORMAL ECG, WHEN COMPARED WITH ECG OF 01NOV2020, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN INFERIOR LEADS, NONSPECIFIC T WAVE ABNORMALITY NOW EVIDENT IN LATERAL LEADS. ECHO 2D DOPPLER-COLOR FLOW 16NOV2020 INTERPRETATION: THERE IS MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY, LEFT VENTRICULAR SYSTOLIC FUNCTION IS NORMAL, EJECTION FRACTION= 60-65%, GRADE I DIASTOLIC DYSFUNCTION, (ABNORMAL RELAXATION PATTERN), RIGHT VENTRICULAR SYSTOLIC PRESSURE IS NORMAL, THERE IS NO PERICARDIAL EFFUSION. CT HEAD WITHOUT CONTRAST 15NOV2020 FINDINGS: THERE IS ADVANCED PARANASAL SINUS DISEASE WITH MUCOSAL THICKENING AND OPACIFICATION FRONTAL SINUSES ARE NEARLY COMPLETELY OPACIFIED WITH SMALL LEFT FRONTAL SINUS FLUID LEVEL SUGGESTED. RIGHT MAXILLARY SINUS FLUID LEVEL ALSO SUGGESTED. THE MASTOID AIR CELLS ARE WITHOUT SUBSTANTIAL ABNORMALITY. NO SUSPICIOUS CALVARIAL LESIONS. ACUTE ON CHRONIC WIDESPREAD PARANASAL SINUSITIS. CHEST XRAY AP ONLY 15NOV2020	Mariete Rendon (b) (4)	23 Apr 2021 13:58:45

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
FINDINGS: THERE IS NORMAL CARDIOMEDIASTINAL CONTOUR. THE LUNGS ARE WELL EXPANDED AND APPEAR CLEAR WITH THE EXCEPTION OF SOME PERSISTENT SMALL CLUSTERED NODULAR OPACITIES PROJECTING OVER THE LATERAL ASPECT OF THE LEFT MIDLUNG, BUT CANNOT EXCLUDE THAT THIS IS WITHIN THE OVERLYING RIB. NO PLEURAL EFFUSION. NO PNEUMOTHORAX. scattered typical bony degenerative/chronic changes.no acute process seen.' reason for change: Data Entry Error		
User entered 'SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 1.65 Ref Range: 0.4-1.1 mg/dl AND GFR 51 >59 ml/min/1.73m2. CONSISTENT WITH ACUTE KIDNEY FAILURE SECONDARY TO DEHYDRATION THAT RESOLVED BY 17NOV WITH CREATININE LEVELS OF 1.19 ref range: 0.4-1.1 mg/dl AND GFR IN 75 ref range: >59 ml/min/1.73m2.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	23 Apr 2021 13:53:52
User closed query 'PV Query: Please confirm creatinine level reported as 165. Should this be 1.65?' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:23:04
Query 'PV Query: Please confirm creatinine level reported as 165. Should this be 1.65?' answered with 'Data corrected' (Site from Safety).	Mariete Rendon (b) (4)	22 Apr 2021 16:57:09
User entered 'SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 1.65 AND GFR 51 CONSISTENT WITH ACUTE KIDNEY FAILURE secoNDary TO DEHYDRATION THAT RESOLVED BY 17NOV WITH CREATININE LEVELS OF 1.19 AND GFR IN 75.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 16:56:53

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 1.65 AND GFR 31 CONSISTENT WITH ACUTE KIDNEY FAILURE 2ND TO DEHYDRATION THAT RESOLVED BY 10DEC WITH CREATININE LEVELS OF 1.08 AND GFR IN 84.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 16:55:16
User opened query 'PV Query: Please provide dates and results for EKG, echo, and brilin CT scan. ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Apr 2021 12:40:18
User opened query 'PV Query: Please provide units and reference ranges for creatinine and GFR levels if possible.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Apr 2021 18:20:46
User opened query 'PV Query: Please confirm creatinine level reported as 165. Should this be 1.65?' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Apr 2021 18:20:36
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:37:41
User entered 'subject that in the course of admission due to syncope episode had a creatinine of 165 and GFR 31 consistent with acute kidney failure 2nd to dehydration that resolved by 10DEC with creatinine levels of 1.08 and GFR in 84.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:37:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:51:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 19:37:41
User entered '0'	System	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Dec 2020 19:23:05

US3172114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:15:55

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:23
User entered 'USA-US118-2020-mRNA-1273-P301000014'	(b) (4), (b) (6)	12 Apr 2021 20:32:19

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the subject previously experienced acute kidney injury on 15 Nov 2020, Was this SAE (acute kidney injury) considered a worsening of the subject's medical history? If so, please consider updating event term to include disease progression. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:16:59
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 19:46:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 19:46:55
Data point term sent to Coder	System	09 Apr 2021 19:46:13
User entered 'Acute Kidney Injury'	Mariete Rendon (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Dec 2020'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Dec 2020'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 19:58:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 19:58:36
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:58:36
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:45:51
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:41:58
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:15:06
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Apr 2021 19:59:13
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:58:59
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Apr 2021 19:45:51
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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	12 Apr 2021 20:14:31
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).	System	12 Apr 2021 20:14:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Apr 2021 19:59:13
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Apr 2021 19:59:13
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	12 Apr 2021 19:59:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:59:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Apr 2021 19:58:36
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:58:36
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:58:36
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:14:31
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:42:05
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:15:23
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:00:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:58:29
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:45:51
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:42:07
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:15:21
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:00:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 01:58:36
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:45:51
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:00:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:45:51
User entered empty.	Mariete Rendon (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 20:14:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:14:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Apr 2021 19:45:51
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the subject previously experienced acute kidney injury on 15 Nov 2020, please consider adding it to medical history in EDC. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:18:07
User opened query 'PV Query: Please provide units and reference ranges for creatinine and GFR levels if possible.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:16:36
User opened query 'PV Query: Please confirm creatinine level reported as 165. Should this be 1.65?' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:16:22
User opened query 'PV Query: Please send a hospital discharge summary for the hospitalization for 04 Dec 2020 through 11 Dec 2020 and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:16:04
User entered 'SUBJECT THAT IN THE COURSE OF ADMISSION DUE TO SYNCOPE EPISODE HAD A CREATININE OF 165 AND GFR 31 CONSISTENT WITH ACUTE KIDNEY FAILURE 2ND TO DEHYDRATION THAT RESOLVED BY 10DEC WITH CREATININE LEVELS OF 1.08 AND GFR IN 84.' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:14:55
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 19:45:51

US3172114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:14:31

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 18:39:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 18:39:08
Data point term sent to Coder	System	15 Apr 2021 18:36:58
User entered 'diarrhea'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

None

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 18:36:30

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 18:39:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 18:39:10
Data point term sent to Coder	System	15 Apr 2021 18:38:01
User entered 'copd exacerbation'	Jessie Downs (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:37:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:37:45
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:45
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:37:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 18:37:45

US3172114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 18:37:33

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Normocytic anaemia, LLT: Normocytic anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:00:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:00:09
Data point term sent to Coder	System	15 Apr 2021 18:57:30
User entered 'normocytic anemia'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:59:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:59:37
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:59:37
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:57:18
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:59:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:59:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessie Downs (b) (4)	15 Apr 2021 18:59:37
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 18:57:18
User entered empty.	Jessie Downs (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 18:59:37

US3172114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 18:57:18

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Pansinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:21:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:21:58
Data point term sent to Coder	System	15 Apr 2021 19:21:36
User entered 'pansinusitis'	Jessie Downs (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:37:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:37:53
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 16:37:53
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 19:20:54
User entered empty.	Jessie Downs (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	15 Apr 2021 19:21:06
User entered '15 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	15 Apr 2021 19:21:06
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	15 Apr 2021 19:20:54
User entered '15 Nov 2021'	Jessie Downs (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	15 Apr 2021 19:21:06
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	15 Apr 2021 19:20:54
User entered '27 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:20:54

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Lip swelling, LLT: Lip swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 15:07:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 15:07:32
Data point term sent to Coder	System	15 Apr 2021 19:24:41
User entered 'lower lip swelling without airway involvement'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:24:13

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:27:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:27:58
Data point term sent to Coder	System	15 Apr 2021 19:25:42
User entered 'right inguinal hernia'	Jessie Downs (b) (4)	15 Apr 2021 19:25:26
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:37:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:37:35
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 16:37:35
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 19:25:26
User entered empty.	Jessie Downs (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:25:26

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:28:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:28:14
Data point term sent to Coder	System	15 Apr 2021 19:27:45
User entered 'syncope and collapse'	Jessie Downs (b) (4)	15 Apr 2021 19:27:07
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:38:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:38:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 16:38:26
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 19:27:07
User entered empty.	Jessie Downs (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 16:38:26
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 16:38:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0'	System	15 Apr 2021 19:27:07
	Jessie Downs (b) (4)	15 Apr 2021 19:27:07
	(b) (4)	

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:27:07

US3172114

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:37:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:27:07

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:37:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:05

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:51:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:51:15
Data point term sent to Coder	System	17 Aug 2020 12:49:54
User entered 'METFORMIN'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'DIABETES TYPE 2'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '1000'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
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.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 11:48:38
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	17 Aug 2020 12:48:54
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:58:03
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 14:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 12:48:54
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 12:48:54

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 12:51:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 12:51:15
Data point term sent to Coder	System	17 Aug 2020 12:49:55
User entered 'LISINOPRIL'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'HYPERTENSION'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '10'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
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.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 11:48:45
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	17 Aug 2020 12:49:30
User entered 'UN UNK 2015'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:53:19
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 17:22:04
	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 17:22:04
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '11 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:53:19
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4)	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
User entered '2'	System	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
User entered '1'	System	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:19:59
User entered '804 (804)'	System	17 Aug 2020 12:49:30

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 00:07:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 00:07:12
Data point term sent to Coder	System	22 Apr 2021 17:22:37
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:21:45
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:43:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:43:40
Data point term sent to Coder	System	10 Sep 2020 18:43:32
User entered 'ALBUTEROL'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:21:45
User entered 'Chronic Obstructive pulmonary disease (2 puffs)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:21:45
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'ASTHMA'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:45:56
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:37:22
User entered '90' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:37:09
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:40:33
User entered '2' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 17:03:21
User closed query 'Per DM CLR: Please provide the strength of this Con Med in the medication name, and consider recording the number of puffs instead (e.g. Dose = 1; Dose Unit = puff). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 22:32:12
Query 'Per DM CLR: Please provide the strength of this Con Med in the medication name, and consider recording the number of puffs instead (e.g. Dose = 1; Dose Unit = puff). Review and amend as appropriate.' answered with 'Albuterol 90mg base. Dose: 2 puffs, 4-6hours, PRN' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 21:19:15
User entered '2 puffs' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 21:18:26

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the strength of this Con Med in the medication name, and consider recording the number of puffs instead (e.g. Dose = 1; Dose Unit = puff). Review and amend as appropriate.' (Site from DM). User entered '0.083'	(b) (4), (b) (6) Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 09:58:48 10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Feb 2021 19:14:14
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:37:09
	(b) (4)	
User entered 'puff (PUFF)' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Nov 2020 17:03:31
	(b) (4)	
User entered 'Other (OTHER)'	Mariete Rendon (b) (4)	10 Sep 2020 18:43:12
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please be advised that mcg and ug both mean microgram. Please consider amending the dose unit as ug is a selection in the drop down menu.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 10:21:56
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
Query 'Per CDM: Please be advised that mcg and ug both mean microgram. Please consider amending the dose unit as ug is a selection in the drop down menu.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	11 Feb 2021 19:14:26
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	11 Feb 2021 19:14:14
User opened query 'Per CDM: Please be advised that mcg and ug both mean microgram. Please consider amending the dose unit as ug is a selection in the drop down menu.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:47:43
User entered 'mcg' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:37:09
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Please consider recording the number of Puffs instead (e.g. dose=1; other; unit=Puff) and remove the unit information from the dose field. Review and amend as appropriate. Review and update as applicable.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:33:09
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Please consider recording the number of Puffs instead (e.g. dose=1; other; unit=Puff) and remove the unit information from the dose field. Review and amend as appropriate. Review and update as applicable.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	30 Nov 2020 17:03:42
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	30 Nov 2020 17:03:31
User entered 'puffs' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Nov 2020 17:03:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

2142 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Please consider recording the number of Puffs instead (e.g. dose=1; other; unit=Puff) and remove the unit information from the dose field. Review and amend as appropriate. Review and update as applicable. ' (Site from DM). User entered 'PERCENT'	(b) (4), (b) (6)	27 Nov 2020 14:14:55
	Mariete Rendon (b) (4)	10 Sep 2020 18:43:12
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:43:12

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
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)	14 Dec 2020 20:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:24:51
Data point term sent to Coder	System	14 Dec 2020 20:24:04
User entered 'AMLODIPINE'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:23:34
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Per DM CLR: Please review if medications #4 and 5 were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:48:23
Query 'Per DM CLR: Please review if medications #4 and 5 were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'Medication Lisinopril ended and medication was changed to Amlodipine and Carvedilol.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 15:55:12
User opened query 'Per DM CLR: Please review if medications #4 and 5 were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:41:09
User entered 'HYPERTENSION'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '10'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:23:34
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:23:33
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:23:33
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:23:34

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:25:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:25:53
Data point term sent to Coder	System	14 Dec 2020 20:25:14
User entered 'CARVEDILOL'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:24:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 20:24:51
User entered 'HYPERTENSION' reason for change: Jessie Downs	(b) (4)	14 Dec 2020 20:24:51
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:24:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '3.125'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:24:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:37:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:37:59
Data point term sent to Coder	System	14 Dec 2020 20:28:27
User entered 'DICYCLOMINE'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'BLOATING'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '10'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'four times daily (QID)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:28:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:28:44
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:28:44
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 17:28:44
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:27:46

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE;SALMETEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:06:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 17:31:44
Coding entries removed.	Mariete Rendon (b) (4)	22 Apr 2021 17:31:15
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE;SALMETEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:23:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:23:44
	(b) (4)	
Data point term sent to Coder	System	14 Dec 2020 20:31:46
User entered 'FLUTICASONE / SALMETAROL'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 17:31:15
	(b) (4)	
User entered 'Chronic Obstructive Pulmonary Disease' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 17:31:15
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'COPD'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '250/50'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'ug (ug)'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 17:31:15
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 17:31:15
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:41:10
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'Subject suffers from COPD ' (Site from DM).	Jessie Downs (b) (4)	01 Feb 2021 15:50:16
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:42:23
User entered '11 Dec 2020'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:49:10
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '27 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:49:10
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:30:58
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User entered '2'	System	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User entered '1'	System	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:41
User entered '804 (804)'	System	14 Dec 2020 20:30:58

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User closed query 'Per DM CLR: Con Med FLUTICASONE was added/changed on 11 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	05 Mar 2021 08:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Feb 2021 21:21:04
Data point term sent to Coder Coding entries removed.	(b) (4)	
Query 'Per DM CLR: Con Med FLUTICASONE was added/changed on 11 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'Data confirmed as entered - not an ae' (Site from DM).	System	26 Feb 2021 21:20:47
DataPoint Un-verified.	Jessie Downs (b) (4)	26 Feb 2021 21:20:34
DataPoint Verified.	(b) (4)	
User opened query 'Per DM CLR: Con Med FLUTICASONE was added/changed on 11 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	Jessie Downs (b) (4)	26 Feb 2021 21:19:49
	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:19:37
	(b) (4), (b) (6)	18 Feb 2021 19:19:31
	(b) (4), (b) (6)	17 Feb 2021 17:29:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

2228 of 2608

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:33:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:33:47
	(b) (4)	
Data point term sent to Coder	System	14 Dec 2020 20:32:51
User entered 'FLUTICASONE'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:55:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4)	01 Feb 2021 20:42:21
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:43:15
User entered 'ALLERGIC RHINITIS'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '50'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
User closed query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:45:32
Query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	22 Mar 2021 13:51:42
Signature has been broken.	Jessie Downs (b) (4)	22 Mar 2021 13:51:29
User entered 'ug (ug)' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Mar 2021 13:51:29
User opened query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:42:14
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	22 Mar 2021 13:51:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	22 Mar 2021 13:51:29
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'MCG'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 18:57:58
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Mariete Rendon (b) (4)	22 Apr 2021 18:57:58
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:28:07
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'data was updated' (Site from DM).	Jessie Downs (b) (4)	26 Feb 2021 21:20:52
Signature has been broken.	(b) (4)	26 Feb 2021 21:20:34
User entered 'Nasal (NASAL)' reason for change:	Jessie Downs (b) (4)	26 Feb 2021 21:20:34
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:29:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 18:57:58
	(b) (4)	
User entered 'un UNK 2007' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 18:57:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '11 Dec 2020'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:53:54
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '27 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Feb 2021 15:53:54
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:31:49
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User entered empty.	System	22 Apr 2021 18:57:58
User entered '2'	System	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User entered empty.	System	22 Apr 2021 18:57:58
User entered '1'	System	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:39
User entered empty.	System	22 Apr 2021 18:57:58
User entered '804 (804)'	System	14 Dec 2020 20:31:49

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:33:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:33:47
Data point term sent to Coder	System	14 Dec 2020 20:32:51
User entered 'LOPERAMIDE'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'DIARRHEA'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '4'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'three times daily (TID)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 18:58:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 18:58:51
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	22 Apr 2021 18:58:51
	(b) (4)	
User entered '20 Dec 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 18:58:51
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	14 Dec 2020 20:32:33
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
User entered '3'	System	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
User entered '1'	System	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:20:40
User entered '804 (804)'	System	14 Dec 2020 20:32:33

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:34:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:34:42
Data point term sent to Coder	System	14 Dec 2020 20:33:51
User entered 'FERROUS SULFATE'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'ANEMIA'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '325'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	14 Dec 2020 20:33:17
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 18:59:49
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 18:59:49
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:33:17

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Dec 2020 20:34:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Dec 2020 20:34:42
	(b) (4)	
Data point term sent to Coder	System	14 Dec 2020 20:33:52
User entered 'FOLIC ACID'	Jessie Downs (b) (4)	14 Dec 2020 20:33:51
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 13:32:26
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User closed query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:53:17
Query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 13:33:06
User opened query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:39:05
User entered 'NUTRITIONAL SUPPLEMENT'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 19:00:20
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Apr 2021 19:00:20
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:33:51

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:03:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:03:40
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 19:06:27
Coding entries removed.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
Coding entries removed.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
User entered 'Dyphenhydramine' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 19:03:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 19:03:05
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 19:02:20
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 15:48:27
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 19:25:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 19:25:41
Data point term sent to Coder	System	23 Dec 2020 19:25:02
User entered 'loperamide'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #10 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 03:43:28
User entered 'Lower Lip swelling' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #10 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. answered with 'Added in error. Page will be inactivated.' (Site from DM).	Jessie Downs (b) (4)	01 Feb 2021 15:47:48
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #10 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:43:42
User entered 'diarrhea'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '25' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '4'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'three times daily (TID)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '11 Dec 2020'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:06:17
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:24:53
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '3'	System	23 Dec 2020 19:24:53

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '1'	System	23 Dec 2020 19:24:53

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:22
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:02:01
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:47:57
	(b) (4)	
User entered '804 (804)'	System	23 Dec 2020 19:24:53

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:05:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:05:44
Data point term sent to Coder	System	22 Apr 2021 19:08:29
Coding entries removed.	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
Coding entries removed.	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
User entered 'Famotidine' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
Data point term sent to Coder	System	22 Apr 2021 19:07:28
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
Data point term sent to Coder	System	01 Feb 2021 15:46:25
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 20:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 20:19:46
Data point term sent to Coder	System	23 Dec 2020 19:26:04

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ferrous sulphate'	Jessie Downs (b) (4) (b) (4)	23 Dec 2020 19:25:19

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #11 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 04:15:46
User entered 'Lower Lip swelling' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #11 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'Entered in error. Page will be inactivated. ' (Site from DM).	Jessie Downs (b) (4)	01 Feb 2021 15:46:06
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with ongoing Con Med #11 (Start date 11DEC2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:44:06
User entered 'anemia'	Jessie Downs (b) (4)	23 Dec 2020 19:25:19

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '20' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered '325' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered 'mg (mg)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered 'twice daily (BID)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered 'once daily (QD)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	23 Dec 2020 19:25:41
User entered '11 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '23 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Apr 2021 19:07:50
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 19:25:41
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Dec 2020 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:25:19
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:25:19
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
User entered '2'	System	22 Apr 2021 19:07:50
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered '1'	System	23 Dec 2020 19:25:41
User entered empty.	System	23 Dec 2020 19:25:19

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered 'I'	System	23 Dec 2020 19:25:41
User entered empty.	System	23 Dec 2020 19:25:19

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:24
DataPoint activated with code reason code Data required.	Mariete Rendon (b) (4)	22 Apr 2021 19:06:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	01 Feb 2021 15:46:18
	(b) (4)	
User entered '804 (804)'	System	23 Dec 2020 19:25:41
User entered empty.	System	23 Dec 2020 19:25:19

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE, PRODUCTS YNOM: MEDROL DOSEPAK - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 20:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 20:25:49
Data point term sent to Coder	System	23 Dec 2020 19:28:06
User entered 'medrol dose pack'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'copd exacerbation'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	11 Feb 2021 17:12:39
User entered '4' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Feb 2021 17:12:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:54:45
User entered '1'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'mg (mg)' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Feb 2021 17:12:27
User entered 'tablet (TABLET)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '22 Dec 2020'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered '0'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:57
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '27 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 22:43:57
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Dec 2020 19:27:15
	(b) (4)	

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:19:31
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4)	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
User entered empty.	System	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
User entered empty.	System	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:37:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:24:56
User entered empty.	System	23 Dec 2020 19:27:15

US3172114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:37:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 13:51:52

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '15/Dec/2020 10:02'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '02/Feb/2021 13:56'	System	02 Feb 2021 13:56:08

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 13:56:08

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '01/Mar/2021 15:13'	System	01 Mar 2021 20:13:27

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:10
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 20:13:27

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered '12/Apr/2021 16:30'	System	12 Apr 2021 20:31:04

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:23:23
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 20:31:04

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered '13/Apr/2021 11:05'	System	13 Apr 2021 15:05:52

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:23:23
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 15:05:52

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered '15/Apr/2021 09:16'	System	15 Apr 2021 13:16:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:23:23
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 13:16:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '23/Apr/2021 08:32'	System	23 Apr 2021 12:32:05

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 12:32:05

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:17
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'USA-US118-2020-MRNA-1273-P301000013'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Yes (Y)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'No (N)'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Mark'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'Kutner'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:02:16
User entered 'FL'	System	15 Dec 2020 15:00:21

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:20
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:30:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:55:58
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	23 Apr 2021 18:36:32
User entered '7'	System	23 Apr 2021 12:32:05
User entered '6'	System	15 Apr 2021 13:16:35
User entered '5'	System	13 Apr 2021 15:05:52
User entered '4'	System	12 Apr 2021 20:31:04
User entered '3'	System	01 Mar 2021 20:13:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:56:08
User entered '1'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '23/Apr/2021 14:36'	System	23 Apr 2021 18:36:32

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 18:36:32

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '15/Dec/2020 10:03'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:57:52
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '02/Feb/2021 13:58'	System	02 Feb 2021 13:58:08

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:38
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 13:58:08

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered '01/Mar/2021 15:17'	System	01 Mar 2021 20:17:10

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:38
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:20
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 20:17:10

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered '12/Apr/2021 16:33'	System	12 Apr 2021 20:33:13

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:35:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:04:23
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 20:33:13

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered '13/Apr/2021 11:06'	System	13 Apr 2021 15:06:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:35:59
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:04:23
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 15:06:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '22/Apr/2021 15:36'	System	22 Apr 2021 19:36:14

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 11:28:28
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 19:36:14

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'USA-US118-2020-MRNA-1273-P301000014'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'No (N)'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Mark'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'Kutner'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'FL'	System	15 Dec 2020 15:01:35

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:51
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 20:32:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:30:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:03:02
User entered 'US'	System	15 Dec 2020 15:02:36

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 11:28:47
User entered '6'	System	22 Apr 2021 19:36:14
User entered '5'	System	13 Apr 2021 15:06:36
User entered '4'	System	12 Apr 2021 20:33:13
User entered '3'	System	01 Mar 2021 20:17:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:30:04
	(b) (4)	
User entered '2'	System	02 Feb 2021 13:58:08
User entered '1'	System	15 Dec 2020 15:03:11

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:37:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:27
	(b) (4)	
User entered '23/Apr/2021 07:28'	System	23 Apr 2021 11:28:47

US3172114

Folder: SAE USA-US118-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:37:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:27
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 11:28:47