

US3352424 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:11:14

All time stamps listed in this document are displayed in GMT

US3352424

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

Participant ID

US3352424

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

US3352424

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3352424

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3352424

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3352424

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3352424

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Were any significant conditions reported?

Yes ☒

No ☐

US3352424

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Start Year (derived)	1973
Stop Month and Year (derived)	
Stop Year (derived)	

US3352424

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Condition	SURGERY - LASIK (BILATERAL)
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3352424

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	23 SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3352424

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Condition	HYPERTENSION
Start date (dd MMM yyyy)	23 SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3352424

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:02 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:02
Height (<i>xxx.x</i>)	175.0 cm
Weight (<i>xxx.x</i>)	97.6 kg
BMI (<i>xxx.x</i>)	31.86939 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352424

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3352424

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3352424

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 115584

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 ☒

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Height	ND - Not Done
Weight	ND - Not Done

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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)	24 SEP 2020
Time of assessment (00:00-23:59)	15:02 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:02
Temperature (xxx.x)	37.1 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	16:41 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 16:41
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)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 16:11 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 16:11

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

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	15:40 (24 HR)
Collection date and time (derived)	24 SEP 2020 15:40

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	24 SEP 2020 15:35
Nasopharyngeal Swab 2	No		

US3352424

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

98.5 °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

24 SEP 2020 16:42

PC Open Date & Time

24 SEP 2020 16:31

PC Close Date & Time

24 SEP 2020 19:01

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	24 SEP 2020 20:03
PC Open Date & Time	24 SEP 2020 19:56
PC Close Date & Time	25 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 16:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

26 SEP 2020 13:31

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:57

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 16:41

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

29 SEP 2020 17:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

30 SEP 2020 15:23

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

24 SEP 2020 16:43

PC Open Date & Time

24 SEP 2020 16:31

PC Close Date & Time

24 SEP 2020 19:01

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

24 SEP 2020 20:05

PC Open Date & Time

24 SEP 2020 19:56

PC Close Date & Time

25 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

25 SEP 2020 16:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

26 SEP 2020 13:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

27 SEP 2020 18:57

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

28 SEP 2020 16:41

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

29 SEP 2020 17:13

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

30 SEP 2020 15:23

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 16:44
PC Open Date & Time	24 SEP 2020 16:31
PC Close Date & Time	24 SEP 2020 19:01

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 20:07
PC Open Date & Time	24 SEP 2020 19:56
PC Close Date & Time	25 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 16:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:33
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

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 2344

EAB) (1725)

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:58
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:42
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 17:14
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 15:24
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

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

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	27 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT2
------------	--------

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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)	27 OCT 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 10:41
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)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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)	27 OCT 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 12:14
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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) 27 OCT 2020

What was the treatment time? (00:00-23:59) 11:44 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 11:44

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

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

Collection date (dd MMM yyyy)	27 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:15 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	27 OCT 2020 11:15
------------------------------------	-------------------

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:53	27 OCT 2020 10:53
Nasopharyngeal Swab 2	No		

US3352424

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

98.1 °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

27 OCT 2020 12:16

PC Open Date & Time

27 OCT 2020 12:04

PC Close Date & Time

27 OCT 2020 14:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	27 OCT 2020 21:55
PC Open Date & Time	27 OCT 2020 15:29
PC Close Date & Time	28 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 20:01

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

29 OCT 2020 22:00

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

31 OCT 2020 00:49

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

31 OCT 2020 21:22

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

01 NOV 2020 19:09

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

97.6 °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

02 NOV 2020 22:25

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

27 OCT 2020 12:17

PC Open Date & Time

27 OCT 2020 12:04

PC Close Date & Time

27 OCT 2020 14:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

27 OCT 2020 21:57

PC Open Date & Time

27 OCT 2020 15:29

PC Close Date & Time

28 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

28 OCT 2020 20:02

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

29 OCT 2020 22:01

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

31 OCT 2020 00:49

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

31 OCT 2020 21:22

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

01 NOV 2020 19:09

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

02 NOV 2020 22:25

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 12:18
PC Open Date & Time	27 OCT 2020 12:04
PC Close Date & Time	27 OCT 2020 14:34

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 21:59
PC Open Date & Time	27 OCT 2020 15:29
PC Close Date & Time	28 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

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 2344

EAB) (1725)

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 20:04
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

96 of 2344

EAB) (1725)

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 22:06
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

98 of 2344

EAB) (1725)

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

		Yes <input type="checkbox"/>
PC Time stamp	31 OCT 2020 00:50	
PC Open Date & Time	30 OCT 2020 12:00	
PC Close Date & Time	31 OCT 2020 11:59	

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 21:23
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2344

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 19:10
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

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 ☒

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 22:26
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

04 NOV 2020 00:08

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 NOV 2020 00:08
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	24 NOV 2020
--------------------------	-------------

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

Folder OID	VISIT3
------------	--------

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 16:00
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352424

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 NOV 2020

Collection time (00:00-23:59)

16:25 (24 HR)

Collection date and time (derived)

24 NOV 2020 16:25

US3352424

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 00:18:36
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 68
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	28 NOV 2020 23:50:12
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 75
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	06 DEC 2020 19:24:01
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 19:02:31

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:03:08

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 DEC 2020 21:30:16
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 12:45:49

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 21:35:34

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 15:23:43

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 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	23 JAN 2021 21:22:10
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 18:35:21
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 13:58:47

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 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 14:13:50
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 15:10:42

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 15:41:43
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

08 MAR 2021 12:11:16

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

15 MAR 2021 12:38:46

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 18:19:19

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 14:06:37

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

03 APR 2021 23:19:06

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

12 APR 2021 08:22:39

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

17 APR 2021 23:22:07

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

25 APR 2021 20:02:20

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 13:07:28

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 <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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

Patient Cloud Close Date & Time	27 OCT 2021 23:59
---	-------------------

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

Patient Cloud Close Date & Time	29 DEC 2021 23:59
---	-------------------

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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="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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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°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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 <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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	19 NOV 2022 00:01
Patient Cloud Close Date & Time	23 NOV 2022 23:59

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:11:14

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		01 MAR 2021 15:44:33

US3352424

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	26 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 APR 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 15:35
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352424

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

Collection date (dd MMM yyyy)	26 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:48 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 APR 2021 15:48
------------------------------------	-------------------

US3352424

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352424

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:14

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"/>

US3352424

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:11:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352424

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3352424

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

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

US3352424

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Height	
Weight	
BMI (xxx.x)	

US3352424

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 13:45
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 14:45
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)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 18 FEB 2021

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

Treatment Date and Time (derived) 18 FEB 2021 14:23

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

US3352424

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

15:56 (24 HR)

Collection date and time (derived)

19 JAN 2021 15:56

US3352424

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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

Collection date (dd MMM yyyy)	19 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:51
---------------------------------	-------

Collection Date and Time (derived)	19 JAN 2021 15:51
------------------------------------	-------------------

US3352424

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:28

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	20 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	OLD29
------------	-------

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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)	20 MAR 2021
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	20 MAR 2021 12:44
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 MAR 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	20 MAR 2021 13:46
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)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3352424

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 20 MAR 2021

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 20 MAR 2021 13:16

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

What was the frequency of the study treatment dosing? ONCE

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

US3352424

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352424

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:23:42

Generated On: 09 Jun 2021 17:11:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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

Visit date (dd MMM yyyy)	26 APR 2021
--------------------------	-------------

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

Folder OID	OLD57
------------	-------

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 APR 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 15:35
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352424

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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.

US3352424

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

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

Collection date (<i>dd MMM yyyy</i>)	26 APR 2021
--	-------------

Collection time (<i>00:00-23:59</i>)	15:48 (24 HR)
--	---------------

Collection date and time (derived)	26 APR 2021 15:48
------------------------------------	-------------------

US3352424

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:23:25

Generated On: 09 Jun 2021 17:11:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	SINUS TACHYCARDIA
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)	05 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	18 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

SUBJECT REPORTED TODAY
GOING TO THE ER ON
SATURDAY 10/17/20 AT 16:00
AFTER HAVING ELEVATED
BLOOD PRESSURE AND
TACHYCARDIA. HE WAS TOLD
BY THE ER PHYSICIAN THAT
HIS POTASSIUM WAS LOW .
SUBJECT REPORTED THAT HE
WAS GIVEN POTASSIUM AND
IV FLUIDS AND FINALLY
DISCHARGED SUNDAY AT
APPROXIMATE 19:00. TODAY
HE REPORTS FEELING WELL
AND DENIES ANY OTHER
HEALTH CHANGES. UPON
FURTHER INTERVIEW WITH
SUBJECT HE REPORTS
STARTING NEW TREATMENT
FOR HYPERLIPIDEMIA AND
HYPERTENSION 10/05/2020
BASED ON RECENT
LABORATORY RESULTS AND
FOLLOW UP WITH HIS
PRIMARY DOCTOR.

VITAL SIGNS BEFORE DOSING
B/P 138/ 89, HR 97.
30 MINUTES POST DOSE B/P
127/86 , HR 94.

PENDING TO REVIEW MEDICAL
RECORDS AT THIS TIME. IN
VIEW OF THE PRELIMINARY
INFORMATION THAT WE HAVE
IT SEEMS THAT EVENT OF
TACHYCARDIA AND
HYPERTENSION IS NOT
RELATED TO STUDY PRODUCT
INSTEAD FROM PREEXISTING
CONDITIONS NOT DIAGNOSED
PRIOR TO DOSING.

Serious Adverse Event Derived (CSA Programming Field Only)

1

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	WORSENING OF HYPERTENSION
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)	05 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	18 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	354 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

SUBJECT REPORTED TODAY
GOING TO THE ER ON
SATURDAY 10/17/20 AT 16:00
AFTER HAVING ELEVATED
BLOOD PRESSURE AND
TACHYCARDIA. HE WAS TOLD
BY THE ER PHYSICIAN THAT
HIS POTASSIUM WAS LOW .
SUBJECT REPORTED THAT HE
WAS GIVEN POTASSIUM AND
IV FLUIDS AND FINALLY
DISCHARGED SUNDAY AT
APPROXIMATE 19:00. TODAY
HE REPORTS FEELING WELL
AND DENIES ANY OTHER
HEALTH CHANGES. UPON
FURTHER INTERVIEW WITH
SUBJECT HE REPORTS
STARTING NEW TREATMENT
FOR HYPERLIPIDEMIA AND
HYPERTENSION 10/05/2020
BASED ON RECENT
LABORATORY RESULTS AND
FOLLOW UP WITH HIS
PRIMARY DOCTOR.

VITAL SIGNS BEFORE DOSING
B/P 138/ 89, HR 97.
30 MINUTES POST DOSE B/P
127/86 , HR 94.

PENDING TO REVIEW MEDICAL
RECORDS AT THIS TIME. IN
VIEW OF THE PRELIMINARY
INFORMATION THAT WE HAVE
IT SEEMS THAT EVENT OF
TACHYCARDIA AND
HYPERTENSION IS NOT
RELATED TO STUDY PRODUCT
INSTEAD FROM PREEXISTING
CONDITIONS NOT DIAGNOSED
PRIOR TO DOSING.

Serious Adverse Event Derived (CSA Programming Field Only)

1

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	HYPOKALEMIA
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)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	18 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

SUBJECT REPORTED TODAY
GOING TO THE ER ON
SATURDAY 10/17/20 AT 16:00
AFTER HAVING ELEVATED
BLOOD PRESSURE AND
TACHYCARDIA. HE WAS TOLD
BY THE ER PHYSICIAN THAT
HIS POTASSIUM WAS LOW .
SUBJECT REPORTED THAT HE
WAS GIVEN POTASSIUM AND
IV FLUIDS AND FINALLY
DISCHARGED SUNDAY AT
APPROXIMATE 19:00. TODAY
HE REPORTS FEELING WELL
AND DENIES ANY OTHER
HEALTH CHANGES. UPON
FURTHER INTERVIEW WITH
SUBJECT HE REPORTS
STARTING NEW TREATMENT
FOR HYPERLIPIDEMIA AND
HYPERTENSION 10/05/2020
BASED ON RECENT
LABORATORY RESULTS AND
FOLLOW UP WITH HIS
PRIMARY DOCTOR.

VITAL SIGNS BEFORE DOSING
B/P 138/ 89, HR 97.
30 MINUTES POST DOSE B/P
127/86 , HR 94.

PENDING TO REVIEW MEDICAL
RECORDS AT THIS TIME. IN
VIEW OF THE PRELIMINARY
INFORMATION THAT WE HAVE
IT SEEMS THAT EVENT OF
TACHYCARDIA AND
HYPERTENSION IS NOT
RELATED TO STUDY PRODUCT
INSTEAD FROM PREEXISTING
CONDITIONS NOT DIAGNOSED
PRIOR TO DOSING.

Serious Adverse Event Derived (CSA Programming Field Only)

1

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	HYPONATREMIA
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)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	18 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

SUBJECT REPORTED TODAY
GOING TO THE ER ON
SATURDAY 10/17/20 AT 16:00
AFTER HAVING ELEVATED
BLOOD PRESSURE AND
TACHYCARDIA. HE WAS TOLD
BY THE ER PHYSICIAN THAT
HIS POTASSIUM WAS LOW .
SUBJECT REPORTED THAT HE
WAS GIVEN POTASSIUM AND
IV FLUIDS AND FINALLY
DISCHARGED SUNDAY AT
APPROXIMATE 19:00. TODAY
HE REPORTS FEELING WELL
AND DENIES ANY OTHER
HEALTH CHANGES. UPON
FURTHER INTERVIEW WITH
SUBJECT HE REPORTS
STARTING NEW TREATMENT
FOR HYPERLIPIDEMIA AND
HYPERTENSION 10/05/2020
BASED ON RECENT
LABORATORY RESULTS AND
FOLLOW UP WITH HIS
PRIMARY DOCTOR.

VITAL SIGNS BEFORE DOSING
B/P 138/ 89, HR 97.
30 MINUTES POST DOSE B/P
127/86 , HR 94.

PENDING TO REVIEW MEDICAL
RECORDS AT THIS TIME. IN
VIEW OF THE PRELIMINARY
INFORMATION THAT WE HAVE
IT SEEMS THAT EVENT OF
TACHYCARDIA AND
HYPERTENSION IS NOT
RELATED TO STUDY PRODUCT
INSTEAD FROM PREEXISTING
CONDITIONS NOT DIAGNOSED
PRIOR TO DOSING.

Serious Adverse Event Derived (CSA Programming Field Only)

1

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2344

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:23:18

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

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

Yes ☒

No ☐

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

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication SEROQUEL (QUETIAPINE)

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

AT BEDTIME

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

PRODUCTION RELEASE (v12.003

367 of 2344

EAB) (1725)

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication DEPAKOTE (SODIUM VALPROATE)

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication TERAZOSIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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)

371 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication GEMFIBROZIL

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication CLORTALIDONA

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020	
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"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication GASTRO REFLUX PREVENTION

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)

377 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication LOSARTAN POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERTESION

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)

379 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 OCT 2020	
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"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication VYTORIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10/20

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)

381 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication METOPROLOL ER

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 162

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 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication POTASSIUM BICARB CITRIC
ACID

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 40

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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 checked="" 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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

Name of Medication LOSARTAIN POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication SINUS TACHYCARDIA

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 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:23:26

Generated On: 09 Jun 2021 17:11:14

	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)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:23:27

Generated On: 09 Jun 2021 17:11:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 OCT 2020	CHEST X-RAY	Diagnostic	
17 OCT 2020	12-LEAD ECG	Diagnostic	
18 OCT 2020	ECHOCARDIOGRAM	Diagnostic	
17 OCT 2020	SAFETY LABS	Adverse Event	

US3352424

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:11:14

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

US3352424

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:11:14

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 ☐

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/OCT/2020 17:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/NOV/2020 17:29
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

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/DEC/2020 16:04
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

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/DEC/2020 15:28
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

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 11:31
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

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:23:29

Generated On: 09 Jun 2021 17:11:14

SAEID	USA-US066-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:10
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

US3352424 (Prod: Research Centers of America - ERG)

US3352424

Form: Participant Creation

Generated On: 09 Jun 2021 17:11:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'US3352424'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:14:08

US3352424

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:14:09

US3352424

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'SCRN'	System	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:14:10

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '53'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'YEARS'	System	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '53'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Male (M)'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Sep 2020'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2020'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:14:09

US3352424

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'I'	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:11:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:29:08

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:36:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:36:39
Data point term sent to Coder	System	24 Sep 2020 21:35:56
User entered 'MYOPIA'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'UN UNK 1973'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of LASIK (BILATERAL) was performed in UN UNK 2009. Please review and update if appropriate. Otherwise, clarify.	(b) (4), (b) (6)	09 Nov 2020 12:27:41
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of LASIK (BILATERAL) was performed in UN UNK 2009. Please review and update if appropriate. Otherwise, clarify.	(b) (4), (b) (6)	17 Oct 2020 18:56:59
' (Site from DM).		
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 1973'	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '1973'	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:36:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:36:39
Data point term sent to Coder	System	24 Sep 2020 21:35:55
User entered 'DEPRESSION'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 2010'	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2010'	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:37:40
Data point term sent to Coder	System	24 Sep 2020 21:36:59
User entered 'BIPOLAR'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 2010'	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2010'	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:32:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:32:52
Data point term sent to Coder	System	24 Sep 2020 21:38:02
User entered 'SURGERY - LASIK (BILATERAL)'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'UN UNK 2009'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'UN UNK 2009'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 17:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 17:41:34
Data point term sent to Coder	System	27 Oct 2020 17:40:45
User entered 'anxiety'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'un UNK 2010'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Jan 2010'	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2010'	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:18:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:18:30
Data point term sent to Coder	System	30 Dec 2020 14:17:40
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '23 Sep 2020'	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Sep 2020'	System	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2020'	System	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	30 Dec 2020 14:17:40

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
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)	30 Dec 2020 14:19:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 14:19:31
Data point term sent to Coder	System	30 Dec 2020 14:18:41
User entered 'Hypertension'	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '23 Sep 2020'	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'Sep 2020'	System	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '2020'	System	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered empty.	System	30 Dec 2020 14:18:02

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:02'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '24 Sep 2020 15:02'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '175.0' cm	(b) (4), (b) (6)	24 Sep 2020 21:29:52
DataPoint set to visible.	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '97.6' kg	(b) (4), (b) (6)	24 Sep 2020 21:29:52
DataPoint set to visible.	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered '31.86939'	System	24 Sep 2020 21:29:52
DataPoint set to visible.	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'kg/m2'	System	24 Sep 2020 21:29:52
DataPoint set to visible.	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'bpm'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'breaths/min'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'mmHg'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User entered 'mmHg'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04

US3352424

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:30:01

US3352424

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:30:01

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:04
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:30:55

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:30:55

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 21:30:55

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'VISIT1'	System	24 Sep 2020 21:30:55

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '115584'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13
DataPoint set to visible.	System	24 Sep 2020 20:15:22

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:02'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered '24 Sep 2020 15:02'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '37.1' C	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '97'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'bpm'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '14'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'breaths/min'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '138'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '89'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '16:41'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered '24 Sep 2020 16:41'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '36.9' C	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '94'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'bpm'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'breaths/min'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '127'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '86'	(b) (4), (b) (6)	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:32:45

US3352424

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:32:45

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '16:11'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered '24 Sep 2020 16:11'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'ONCE'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:33:02

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:33:02

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:40'	(b) (4), (b) (6)	24 Sep 2020 21:33:02

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered '24 Sep 2020 15:40'	System	24 Sep 2020 21:33:02

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:35'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered '24 Sep 2020 15:35'	System	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered empty.	System	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:33:17

US3352424

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:28
User entered 'I'	System	24 Sep 2020 21:33:17

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:42:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '05f82cae-e3ce-49ab-b564-892615855202' User entered 'Yes (Y)'	System	24 Sep 2020 20:42:37
	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:42:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '05f82cae-e3ce-49ab-b564-892615855202' User entered '98.5'	System	24 Sep 2020 20:42:37
	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:42:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '05f82cae-e3ce-49ab-b564-892615855202' User entered 'No (N)'	System	24 Sep 2020 20:42:37
	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:42:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '05f82cae-e3ce-49ab-b564-892615855202' User entered '24 Sep 2020 16:42'	System	24 Sep 2020 20:42:37
	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 16:31'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:01'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:03:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3e3c7b6f-f1a2-45f6-b514-4d4c51705563' User entered 'Yes (Y)'	System	25 Sep 2020 00:03:41
	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:03:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3e3c7b6f-f1a2-45f6-b514-4d4c51705563' User entered '98.6'	System	25 Sep 2020 00:03:41
	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:03:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3e3c7b6f-f1a2-45f6-b514-4d4c51705563' User entered 'No (N)'	System	25 Sep 2020 00:03:41
	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:03:39', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3e3c7b6f-f1a2-45f6-b514-4d4c51705563' User entered '24 Sep 2020 20:03'	System	25 Sep 2020 00:03:41
	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:56'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 2'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:00:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b6fd8df2-36f3-45f8-bd6a-0ca1d1e80548' User entered 'Yes (Y)'	System	25 Sep 2020 20:01:22
	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:00:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b6fd8df2-36f3-45f8-bd6a-0ca1d1e80548' User entered '98.0'	System	25 Sep 2020 20:01:22
	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:01:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b6fd8df2-36f3-45f8-bd6a-0ca1d1e80548'	System	25 Sep 2020 20:01:22
User entered 'No (N)'	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:01:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b6fd8df2-36f3-45f8-bd6a-0ca1d1e80548'	System	25 Sep 2020 20:01:22
User entered '25 Sep 2020 16:01'	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 3'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:31:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '5311024c-5d4d-4f79-b64f-541257715ecb' User entered 'Yes (Y)'	System	26 Sep 2020 17:32:00
	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:31:31', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '5311024c-5d4d-4f79-b64f-541257715ecb' User entered '98.5'	System	26 Sep 2020 17:32:00
	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:31:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '5311024c-5d4d-4f79-b64f-541257715ecb' User entered 'No (N)'	System	26 Sep 2020 17:32:00
	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:31:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '5311024c-5d4d-4f79-b64f-541257715ecb' User entered '26 Sep 2020 13:31'	System	26 Sep 2020 17:32:00
	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 4'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:55:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3cb37bdd-7a8b-4e72-ae70-66a1f7630f02' User entered 'Yes (Y)'	System	27 Sep 2020 22:57:08
	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:56:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3cb37bdd-7a8b-4e72-ae70-66a1f7630f02' User entered '99.4'	System	27 Sep 2020 22:57:08
	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:56:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3cb37bdd-7a8b-4e72-ae70-66a1f7630f02' User entered 'No (N)'	System	27 Sep 2020 22:57:08
	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:03', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3cb37bdd-7a8b-4e72-ae70-66a1f7630f02' User entered '27 Sep 2020 18:57'	System	27 Sep 2020 22:57:08
	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 5'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:39:59', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e1f6fc72-8afe-488f-b402-3a150008036d' User entered 'Yes (Y)'	System	28 Sep 2020 20:41:29
	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:12', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e1f6fc72-8afe-488f-b402-3a150008036d' User entered '98.8'	System	28 Sep 2020 20:41:29
	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e1f6fc72-8afe-488f-b402-3a150008036d' User entered 'No (N)'	System	28 Sep 2020 20:41:29
	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e1f6fc72-8afe-488f-b402-3a150008036d' User entered '28 Sep 2020 16:41'	System	28 Sep 2020 20:41:29
	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 6'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:10:49', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '199c7dbd-3cc7-459c-bc6d-2da37296ecce' User entered 'Yes (Y)'	System	29 Sep 2020 21:12:34
	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:11:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '199c7dbd-3cc7-459c-bc6d-2da37296ecce' User entered '98.3'	System	29 Sep 2020 21:12:34
	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:12:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '199c7dbd-3cc7-459c-bc6d-2da37296ecce' User entered 'No (N)'	System	29 Sep 2020 21:12:34
	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:12:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '199c7dbd-3cc7-459c-bc6d-2da37296ecce' User entered '29 Sep 2020 17:12'	System	29 Sep 2020 21:12:34
	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 7'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:11', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c858455-df78-476d-969f-b38f0a1fbf2e' User entered 'Yes (Y)'	System	30 Sep 2020 19:23:32
	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c858455-df78-476d-969f-b38f0a1fbf2e' User entered '98.3'	System	30 Sep 2020 19:23:32
	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c858455-df78-476d-969f-b38f0a1fbf2e' User entered 'No (N)'	System	30 Sep 2020 19:23:32
	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:29', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c858455-df78-476d-969f-b38f0a1fbf2e' User entered '30 Sep 2020 15:23'	System	30 Sep 2020 19:23:32
	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:42:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e4594aa4-e06b-459d-b410-79e67c5e9eb7' User entered 'None (1)'	System	24 Sep 2020 20:43:20
	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:02', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e4594aa4-e06b-459d-b410-79e67c5e9eb7' User entered 'No (N)'	System	24 Sep 2020 20:43:20
	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e4594aa4-e06b-459d-b410-79e67c5e9eb7' User entered 'No (N)'	System	24 Sep 2020 20:43:20
	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:12', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e4594aa4-e06b-459d-b410-79e67c5e9eb7' User entered 'None (1)'	System	24 Sep 2020 20:43:20
	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e4594aa4-e06b-459d-b410-79e67c5e9eb7' User entered '24 Sep 2020 16:43'	System	24 Sep 2020 20:43:20
	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 16:31'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:01'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:04:29', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8dfb2ecd-43da-430b-bb38-1f2010f61d7c' User entered 'None (1)'	System	25 Sep 2020 00:05:51
	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:04:36', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8dfb2ecd-43da-430b-bb38-1f2010f61d7c' User entered 'No (N)'	System	25 Sep 2020 00:05:51
	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:05:28', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8dfb2ecd-43da-430b-bb38-1f2010f61d7c' User entered 'No (N)'	System	25 Sep 2020 00:05:51
	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:05:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8dfb2ecd-43da-430b-bb38-1f2010f61d7c' User entered 'None (1)'	System	25 Sep 2020 00:05:51
	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:05:49', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8dfb2ecd-43da-430b-bb38-1f2010f61d7c' User entered '24 Sep 2020 20:05'	System	25 Sep 2020 00:05:51
	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:56'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 2'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:01:52', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b798807-df67-4515-8439-7d2b265c9dd0'	System	25 Sep 2020 20:02:40
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 20:02:40

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:02:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b798807-df67-4515-8439-7d2b265c9dd0'	System	25 Sep 2020 20:02:40
User entered 'No (N)'	System	25 Sep 2020 20:02:40

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:02:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b798807-df67-4515-8439-7d2b265c9dd0'	System	25 Sep 2020 20:02:40
User entered 'No (N)'	System	25 Sep 2020 20:02:40

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:02:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b798807-df67-4515-8439-7d2b265c9dd0'	System	25 Sep 2020 20:02:40
User entered 'None (1)'	System	25 Sep 2020 20:02:40

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:02:37', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b798807-df67-4515-8439-7d2b265c9dd0'	System	25 Sep 2020 20:02:40
User entered '25 Sep 2020 16:02'	System	25 Sep 2020 20:02:40

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 3'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e5aa1715-4dfd-454a-a082-ce6998456ae5' User entered 'None (1)'	System	26 Sep 2020 17:32:49
	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e5aa1715-4dfd-454a-a082-ce6998456ae5' User entered 'No (N)'	System	26 Sep 2020 17:32:49
	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e5aa1715-4dfd-454a-a082-ce6998456ae5' User entered 'No (N)'	System	26 Sep 2020 17:32:49
	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:37', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e5aa1715-4dfd-454a-a082-ce6998456ae5' User entered 'None (1)'	System	26 Sep 2020 17:32:49
	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:46', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e5aa1715-4dfd-454a-a082-ce6998456ae5' User entered '26 Sep 2020 13:32'	System	26 Sep 2020 17:32:49
	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 4'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:11', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0443da85-924b-4f68-a00a-50ffff51d303'	System	27 Sep 2020 22:57:32
User entered 'None (1)'	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0443da85-924b-4f68-a00a-50ffff51d303' User entered 'No (N)'	System	27 Sep 2020 22:57:32
	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:18', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0443da85-924b-4f68-a00a-50ffff51d303' User entered 'No (N)'	System	27 Sep 2020 22:57:32
	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0443da85-924b-4f68-a00a-50ffff51d303'	System	27 Sep 2020 22:57:32
User entered 'None (1)'	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0443da85-924b-4f68-a00a-50ffff51d303' User entered '27 Sep 2020 18:57'	System	27 Sep 2020 22:57:32
	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 5'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '28f86b5f-aa0a-4a2e-8d71-cf18d1c97f64' User entered 'None (1)'	System	28 Sep 2020 20:41:49
	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:34', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '28f86b5f-aa0a-4a2e-8d71-cf18d1c97f64' User entered 'No (N)'	System	28 Sep 2020 20:41:49
	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:37', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '28f86b5f-aa0a-4a2e-8d71-cf18d1c97f64'	System	28 Sep 2020 20:41:49
User entered 'No (N)'	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:41', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '28f86b5f-aa0a-4a2e-8d71-cf18d1c97f64'	System	28 Sep 2020 20:41:49
User entered 'None (1)'	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '28f86b5f-aa0a-4a2e-8d71-cf18d1c97f64' User entered '28 Sep 2020 16:41'	System	28 Sep 2020 20:41:49
	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 6'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:12:56', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '148f6175-e195-44d4-972a-2aa5754b09d3' User entered 'None (1)'	System	29 Sep 2020 21:13:28
	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '148f6175-e195-44d4-972a-2aa5754b09d3' User entered 'No (N)'	System	29 Sep 2020 21:13:28
	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '148f6175-e195-44d4-972a-2aa5754b09d3' User entered 'No (N)'	System	29 Sep 2020 21:13:28
	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '148f6175-e195-44d4-972a-2aa5754b09d3' User entered 'None (1)'	System	29 Sep 2020 21:13:28
	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:25', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '148f6175-e195-44d4-972a-2aa5754b09d3' User entered '29 Sep 2020 17:13'	System	29 Sep 2020 21:13:28
	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 7'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:35', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '69af6667-008a-4bcf-b331-7fa1e11175ad'	System	30 Sep 2020 19:24:00
User entered 'None (1)'	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:40', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '69af6667-008a-4bcf-b331-7fa1e11175ad' User entered 'No (N)'	System	30 Sep 2020 19:24:00
	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:44', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '69af6667-008a-4bcf-b331-7fa1e11175ad' User entered 'No (N)'	System	30 Sep 2020 19:24:00
	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:49', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '69af6667-008a-4bcf-b331-7fa1e11175ad' User entered 'None (1)'	System	30 Sep 2020 19:24:00
	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:23:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '69af6667-008a-4bcf-b331-7fa1e11175ad' User entered '30 Sep 2020 15:23'	System	30 Sep 2020 19:24:00
	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:44', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:48', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:51', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:43:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'None (0)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:44:03', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered 'No (N)'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T16:44:07', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3044deae-f5bd-4b78-afed-97916ca0d4ef' User entered '24 Sep 2020 16:44'	System	24 Sep 2020 20:44:09
	System	24 Sep 2020 20:44:09

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 16:31'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:01'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'No interference with activity (1)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'None (0)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'None (0)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:34', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'None (0)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'None (0)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'None (0)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:06:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered 'No (N)'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-24T20:07:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4577a83f-90a9-4d7b-9edc-ed0287c0b7ea' User entered '24 Sep 2020 20:07'	System	25 Sep 2020 00:07:24
	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '24 Sep 2020 19:56'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 2'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:02:52', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'None (0)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:03:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'None (0)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:04:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0'	System	25 Sep 2020 20:05:17
User entered 'No interference with activity (1)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:04:34', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'None (0)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:04:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'None (0)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:04:41', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'None (0)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:05:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered 'No (N)'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-25T16:05:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533f6002-4c3f-4254-875e-bb592a4971e0' User entered '25 Sep 2020 16:05'	System	25 Sep 2020 20:05:17
	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 3'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:32:56', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:02', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:26', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'None (0)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:32', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered 'No (N)'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-26T13:33:39', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1c8e7bfb-0ed7-4a71-9024-dd793cbe3f0d' User entered '26 Sep 2020 13:33'	System	26 Sep 2020 17:33:43
	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 4'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:39', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:52', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:57:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'None (0)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:58:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered 'No (N)'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-27T18:58:09', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c4bbf8b3-fce1-4a6e-9a12-c729a5bd2cef' User entered '27 Sep 2020 18:58'	System	27 Sep 2020 22:58:13
	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 5'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:53', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:41:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:07', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'None (0)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered 'No (N)'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-28T16:42:26', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c7479694-31ed-4c8b-9680-4692ac0a3832' User entered '28 Sep 2020 16:42'	System	28 Sep 2020 20:42:29
	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 6'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:32', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:35', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:45', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:48', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262' User entered 'None (0)'	System	29 Sep 2020 21:14:23
	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:13:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262'	System	29 Sep 2020 21:14:23
User entered 'No (N)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-29T17:14:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '641da09f-f2df-4125-bc6e-a9575cc29262'	System	29 Sep 2020 21:14:23
User entered '29 Sep 2020 17:14'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	24 Sep 2020 20:16:03
User entered 'Day 7'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:08', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'None (0)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:39', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered 'No (N)'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-09-30T15:24:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '549500fc-8788-4075-8094-fea680ef634e' User entered '30 Sep 2020 15:24'	System	30 Sep 2020 19:24:50
	System	30 Sep 2020 19:24:50

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 20:16:03

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 20:16:03

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '2 Oct 2020'	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:45

US3352424

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:26:28
User entered 'I'	System	02 Oct 2020 13:52:45

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '8 Oct 2020'	Yulexis Amestoy (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Yulexis Amestoy (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	08 Oct 2020 19:14:42

US3352424

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:13
User entered 'I'	System	08 Oct 2020 19:14:42

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 21:05:57

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 21:05:57

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 21:05:57

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:05:57

US3352424

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 21:06:00

US3352424

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:14:09
User entered 'I'	System	16 Oct 2020 21:06:00

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:29:56
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 02:26:24
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:21:03
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:30:10

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
Query 'PER CDM-The V2/Day 29 (second injection) visit window is -3/+7 (as noted in protocol on page 111).Kindly consider to verify and update data accordingly else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:55:31
User opened query 'PER CDM-The V2/Day 29 (second injection) visit window is -3/+7 (as noted in protocol on page 111).Kindly consider to verify and update data accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:51:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:29:56
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 02:26:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:21:03
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 17:30:10

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:29:56
DataPoint Un-verified.		04 Nov 2020 02:26:29
DataPoint Verified.		04 Nov 2020 02:21:03
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	27 Oct 2020 17:30:10

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'VISIT2'	System	27 Oct 2020 17:30:10

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '10:41'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '27 Oct 2020 10:41'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '36.8' C	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '105'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'bpm'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '16'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'breaths/min'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '118'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '81'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '12:14'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '27 Oct 2020 12:14'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '36.7' C	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '97'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'bpm'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '16'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'breaths/min'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '114'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '81'	Matthew Muniz (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:05
User entered 'No (N)'	Matthew Muniz (b) (4)	27 Oct 2020 19:08:17

US3352424

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:05
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 19:08:17

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User closed query ' PER CDM-The V2/Day 29 (second injection) visit window is -3/+7 (as noted in protocol on page 111).Kindly consider to verify and update data accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:14:01
Query ' PER CDM-The V2/Day 29 (second injection) visit window is -3/+7 (as noted in protocol on page 111).Kindly consider to verify and update data accordingly else clarify. Thank you.' answered with 'LAST DAY OF ALLOWED WINDOW WAS 29OCT2020.' (Site from DM).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 19:55:13
User opened query ' PER CDM-The V2/Day 29 (second injection) visit window is -3/+7 (as noted in protocol on page 111).Kindly consider to verify and update data accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:55:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered '11:44'	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '27 Oct 2020 11:44'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:10
User entered 'ONCE'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:17
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:25

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:17
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:25

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:17
User entered '11:15'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:25

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '27 Oct 2020 11:15'	System	27 Oct 2020 17:38:25

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:20
User entered '27 Oct 2020'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:20
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:20
User entered '10:53'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '27 Oct 2020 10:53'	System	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:20
User entered 'No (N)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:20
User entered empty.	Matthew Muniz (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered empty.	System	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:25
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	27 Oct 2020 17:38:43

US3352424

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:35:03
User entered '1'	System	27 Oct 2020 17:38:43

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:14:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e80245e3-a910-4295-a3ad-c93caf1662a3' User entered 'Yes (Y)'	System	27 Oct 2020 16:16:34
	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:14:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e80245e3-a910-4295-a3ad-c93caf1662a3' User entered '98.1'	System	27 Oct 2020 16:16:34
	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:16:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e80245e3-a910-4295-a3ad-c93caf1662a3' User entered 'No (N)'	System	27 Oct 2020 16:16:34
	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:16:26', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e80245e3-a910-4295-a3ad-c93caf1662a3' User entered '27 Oct 2020 12:16'	System	27 Oct 2020 16:16:34
	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 12:04'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 14:34'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:53:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e2267c79-0d5c-4aa1-a5e5-721f2804f542' User entered 'Yes (Y)'	System	28 Oct 2020 01:55:32
	System	28 Oct 2020 01:55:32

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:53:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e2267c79-0d5c-4aa1-a5e5-721f2804f542'	System	28 Oct 2020 01:55:32
User entered '98.6'	System	28 Oct 2020 01:55:32

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:53:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e2267c79-0d5c-4aa1-a5e5-721f2804f542'	System	28 Oct 2020 01:55:32
User entered 'No (N)'	System	28 Oct 2020 01:55:32

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:55:28', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e2267c79-0d5c-4aa1-a5e5-721f2804f542'	System	28 Oct 2020 01:55:32
User entered '27 Oct 2020 21:55'	System	28 Oct 2020 01:55:32

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 15:29'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 2'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:00:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6395ab14-1103-4cc3-9f1d-a555ec89b12d' User entered 'Yes (Y)'	System	29 Oct 2020 00:01:30
	System	29 Oct 2020 00:01:30

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:01:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6395ab14-1103-4cc3-9f1d-a555ec89b12d' User entered '98.2'	System	29 Oct 2020 00:01:30
	System	29 Oct 2020 00:01:30

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:01:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6395ab14-1103-4cc3-9f1d-a555ec89b12d' User entered 'No (N)'	System	29 Oct 2020 00:01:30
	System	29 Oct 2020 00:01:30

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:01:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6395ab14-1103-4cc3-9f1d-a555ec89b12d' User entered '28 Oct 2020 20:01'	System	29 Oct 2020 00:01:30
	System	29 Oct 2020 00:01:30

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 3'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:00:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fcab080a-c8c0-4979-a5cf-f19734898747' User entered 'Yes (Y)'	System	30 Oct 2020 02:00:59
	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:00:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fcab080a-c8c0-4979-a5cf-f19734898747' User entered '98.1'	System	30 Oct 2020 02:00:59
	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:00:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fcab080a-c8c0-4979-a5cf-f19734898747' User entered 'No (N)'	System	30 Oct 2020 02:00:59
	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:00:56', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fcab080a-c8c0-4979-a5cf-f19734898747' User entered '29 Oct 2020 22:00'	System	30 Oct 2020 02:00:59
	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 4'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:48:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '80bf3a0d-5df7-40a5-babb-88fa9faa5fe2' User entered 'Yes (Y)'	System	31 Oct 2020 04:49:04
	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:48:53', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '80bf3a0d-5df7-40a5-babb-88fa9faa5fe2' User entered '98.6'	System	31 Oct 2020 04:49:04
	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:48:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '80bf3a0d-5df7-40a5-babb-88fa9faa5fe2'	System	31 Oct 2020 04:49:04
User entered 'No (N)'	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:02', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '80bf3a0d-5df7-40a5-babb-88fa9faa5fe2'	System	31 Oct 2020 04:49:04
User entered '31 Oct 2020 00:49'	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 5'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:20:18', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'bcf588ac-9789-4319-a5d1-125a9efec0e9' User entered 'Yes (Y)'	System	01 Nov 2020 01:22:15
	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'bcf588ac-9789-4319-a5d1-125a9efec0e9' User entered '98.3'	System	01 Nov 2020 01:22:15
	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:08', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'bcf588ac-9789-4319-a5d1-125a9efec0e9'	System	01 Nov 2020 01:22:15
User entered 'No (N)'	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'bcf588ac-9789-4319-a5d1-125a9efec0e9' User entered '31 Oct 2020 21:22'	System	01 Nov 2020 01:22:15
	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 6'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:08:51', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fdf1d333-275d-4dc0-99e4-ec7f271d3962'	System	02 Nov 2020 00:09:12
User entered 'Yes (Y)'	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fdf1d333-275d-4dc0-99e4-ec7f271d3962' User entered '98.1'	System	02 Nov 2020 00:09:12
	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fdf1d333-275d-4dc0-99e4-ec7f271d3962'	System	02 Nov 2020 00:09:12
User entered 'No (N)'	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:09', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'fdf1d333-275d-4dc0-99e4-ec7f271d3962' User entered '01 Nov 2020 19:09'	System	02 Nov 2020 00:09:12
	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 7'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3dead65b-7bd1-4626-9c80-5bc202b6d93d' User entered 'Yes (Y)'	System	03 Nov 2020 03:25:33
	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3dead65b-7bd1-4626-9c80-5bc202b6d93d' User entered '97.6'	System	03 Nov 2020 03:25:33
	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:28', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3dead65b-7bd1-4626-9c80-5bc202b6d93d' User entered 'No (N)'	System	03 Nov 2020 03:25:33
	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:31', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3dead65b-7bd1-4626-9c80-5bc202b6d93d' User entered '02 Nov 2020 22:25'	System	03 Nov 2020 03:25:33
	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:16:41', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9752d1b8-af0f-4507-87b5-868d4c11ea02'	System	27 Oct 2020 16:17:20
User entered 'None (1)'	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:16:49', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9752d1b8-af0f-4507-87b5-868d4c11ea02' User entered 'No (N)'	System	27 Oct 2020 16:17:20
	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:16:59', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9752d1b8-af0f-4507-87b5-868d4c11ea02' User entered 'No (N)'	System	27 Oct 2020 16:17:20
	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9752d1b8-af0f-4507-87b5-868d4c11ea02'	System	27 Oct 2020 16:17:20
User entered 'None (1)'	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9752d1b8-af0f-4507-87b5-868d4c11ea02' User entered '27 Oct 2020 12:17'	System	27 Oct 2020 16:17:20
	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 12:04'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 14:34'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:55:46', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '759c005e-f677-448b-8e78-24c1cf09cf7e' User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 01:57:45
	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:56:48', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '759c005e-f677-448b-8e78-24c1cf09cf7e' User entered 'No (N)'	System	28 Oct 2020 01:57:45
	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:57:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '759c005e-f677-448b-8e78-24c1cf09cf7e' User entered 'No (N)'	System	28 Oct 2020 01:57:45
	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:57:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '759c005e-f677-448b-8e78-24c1cf09cf7e' User entered 'None (1)'	System	28 Oct 2020 01:57:45
	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:57:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '759c005e-f677-448b-8e78-24c1cf09cf7e' User entered '27 Oct 2020 21:57'	System	28 Oct 2020 01:57:45
	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 15:29'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 2'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fe9a040-cb01-4c92-9448-959b1eb5463f' User entered 'None (1)'	System	29 Oct 2020 00:02:45
	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fe9a040-cb01-4c92-9448-959b1eb5463f' User entered 'No (N)'	System	29 Oct 2020 00:02:45
	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fe9a040-cb01-4c92-9448-959b1eb5463f' User entered 'No (N)'	System	29 Oct 2020 00:02:45
	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:37', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fe9a040-cb01-4c92-9448-959b1eb5463f' User entered 'None (1)'	System	29 Oct 2020 00:02:45
	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fe9a040-cb01-4c92-9448-959b1eb5463f' User entered '28 Oct 2020 20:02'	System	29 Oct 2020 00:02:45
	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 3'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:06', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '06dcab94-9985-4f4b-a909-ae9d91370262' User entered 'None (1)'	System	30 Oct 2020 02:01:40
	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '06dcab94-9985-4f4b-a909-ae9d91370262' User entered 'No (N)'	System	30 Oct 2020 02:01:40
	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:14', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '06dcab94-9985-4f4b-a909-ae9d91370262' User entered 'No (N)'	System	30 Oct 2020 02:01:40
	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '06dcab94-9985-4f4b-a909-ae9d91370262' User entered 'None (1)'	System	30 Oct 2020 02:01:40
	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:37', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '06dcab94-9985-4f4b-a909-ae9d91370262' User entered '29 Oct 2020 22:01'	System	30 Oct 2020 02:01:40
	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 4'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:09', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '77676c63-bf78-4f0e-ac1c-d6fcb9803ae9' User entered 'None (1)'	System	31 Oct 2020 04:49:29
	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '77676c63-bf78-4f0e-ac1c-d6fcb9803ae9' User entered 'No (N)'	System	31 Oct 2020 04:49:29
	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '77676c63-bf78-4f0e-ac1c-d6fcb9803ae9' User entered 'No (N)'	System	31 Oct 2020 04:49:29
	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '77676c63-bf78-4f0e-ac1c-d6fcb9803ae9' User entered 'None (1)'	System	31 Oct 2020 04:49:29
	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:27', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '77676c63-bf78-4f0e-ac1c-d6fcb9803ae9' User entered '31 Oct 2020 00:49'	System	31 Oct 2020 04:49:29
	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 5'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b239e9ec-75c9-4175-a913-2ebc979d8782' User entered 'None (1)'	System	01 Nov 2020 01:22:42
	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b239e9ec-75c9-4175-a913-2ebc979d8782' User entered 'No (N)'	System	01 Nov 2020 01:22:42
	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:25', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b239e9ec-75c9-4175-a913-2ebc979d8782' User entered 'No (N)'	System	01 Nov 2020 01:22:42
	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b239e9ec-75c9-4175-a913-2ebc979d8782' User entered 'None (1)'	System	01 Nov 2020 01:22:42
	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b239e9ec-75c9-4175-a913-2ebc979d8782' User entered '31 Oct 2020 21:22'	System	01 Nov 2020 01:22:42
	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 6'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a47d0d58-8e45-49e8-8660-202492277cc7' User entered 'None (1)'	System	02 Nov 2020 00:09:34
	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:18', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a47d0d58-8e45-49e8-8660-202492277cc7' User entered 'No (N)'	System	02 Nov 2020 00:09:34
	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a47d0d58-8e45-49e8-8660-202492277cc7' User entered 'No (N)'	System	02 Nov 2020 00:09:34
	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a47d0d58-8e45-49e8-8660-202492277cc7' User entered 'None (1)'	System	02 Nov 2020 00:09:34
	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a47d0d58-8e45-49e8-8660-202492277cc7' User entered '01 Nov 2020 19:09'	System	02 Nov 2020 00:09:34
	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 7'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:40', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '34f847f4-af5b-4482-a201-2c9c6e582214' User entered 'None (1)'	System	03 Nov 2020 03:25:58
	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '34f847f4-af5b-4482-a201-2c9c6e582214' User entered 'No (N)'	System	03 Nov 2020 03:25:58
	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:46', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '34f847f4-af5b-4482-a201-2c9c6e582214'	System	03 Nov 2020 03:25:58
User entered 'No (N)'	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:51', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '34f847f4-af5b-4482-a201-2c9c6e582214' User entered 'None (1)'	System	03 Nov 2020 03:25:58
	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:25:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '34f847f4-af5b-4482-a201-2c9c6e582214' User entered '02 Nov 2020 22:25'	System	03 Nov 2020 03:25:58
	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:39', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:46', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:17:53', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:18:02', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:18:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'None (0)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:18:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered 'No (N)'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T12:18:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'eaeffc25-bf72-4907-b0e4-5707f03dee48' User entered '27 Oct 2020 12:18'	System	27 Oct 2020 16:18:27
	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 12:04'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 14:34'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:57:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'No interference with activity (1)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'No interference with activity (1)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:30', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'None (0)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:36', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'None (0)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'None (0)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:48', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'None (0)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:58:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered 'No (N)'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-27T21:59:03', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e01ca556-58e2-4c98-91ab-e62f7e61db21' User entered '27 Oct 2020 21:59'	System	28 Oct 2020 01:59:08
	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '27 Oct 2020 15:29'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 2'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:02:50', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:03:03', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:03:08', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:03:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:03:26', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:03:29', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered 'None (0)'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:04:11', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80'	System	29 Oct 2020 00:04:19
User entered 'No (N)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-28T20:04:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f0a5d4cf-3de2-4dd4-bb53-f4ef94619d80' User entered '28 Oct 2020 20:04'	System	29 Oct 2020 00:04:19
	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 3'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:46', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:50', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:01:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:02:02', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:02:18', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'None (0)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:06:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered 'No (N)'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-29T22:06:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b3ac0cb-066b-4876-ae5b-b1520a21e9c0' User entered '29 Oct 2020 22:06'	System	30 Oct 2020 02:06:26
	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 4'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:49:58', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0'	System	31 Oct 2020 04:50:53
User entered 'No interference with activity (1)'	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'None (0)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:09', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'None (0)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:14', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'None (0)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'None (0)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'None (0)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered 'Yes (Y)'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T00:50:51', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7788f97-0013-407e-9ffc-cadb20c37bc0' User entered '31 Oct 2020 00:50'	System	31 Oct 2020 04:50:53
	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 5'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:53', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406'	System	01 Nov 2020 01:23:26
User entered 'No interference with activity (1)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:22:56', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'None (0)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'None (0)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'None (0)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:07', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'None (0)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'None (0)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered 'No (N)'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-10-31T21:23:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7133e2c1-9f23-4704-aaa2-a7906b7f5406' User entered '31 Oct 2020 21:23'	System	01 Nov 2020 01:23:26
	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 6'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183'	System	02 Nov 2020 00:10:13
User entered 'No interference with activity (1)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'None (0)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:50', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'None (0)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:53', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'None (0)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'None (0)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:09:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'None (0)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:10:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered 'No (N)'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-01T19:10:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '867277a9-1b0f-4536-88ba-3516c3b7d183' User entered '01 Nov 2020 19:10'	System	02 Nov 2020 00:10:13
	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	27 Oct 2020 15:51:44
User entered 'Day 7'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:12', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876'	System	03 Nov 2020 03:26:40
User entered 'No interference with activity (1)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:15', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'None (0)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:17', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'None (0)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:19', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'None (0)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'None (0)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'None (0)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered 'No (N)'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-02T22:26:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f84f5a91-584c-405f-a056-abbf19e99876' User entered '02 Nov 2020 22:26'	System	03 Nov 2020 03:26:40
	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 15:51:44

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	02 Nov 2020 00:10:13
User entered 'Day 8'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-04T00:08:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '00a20d86-291e-4e02-abc5-2b389dd238d3' User entered 'None (0)'	System	04 Nov 2020 05:08:13
	System	04 Nov 2020 05:08:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-04T00:08:12', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '00a20d86-291e-4e02-abc5-2b389dd238d3' User entered '04 Nov 2020 00:08'	System	04 Nov 2020 05:08:13
	System	04 Nov 2020 05:08:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
Data entry locked.	System	02 Nov 2020 00:10:13
User entered 'Day 8'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

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)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-04T00:08:20', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1e9ce858-63f3-4764-8cc1-9285d9ec7cb1' User entered 'No (N)'	System	04 Nov 2020 05:08:27
	System	04 Nov 2020 05:08:27

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-04T00:08:25', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1e9ce858-63f3-4764-8cc1-9285d9ec7cb1' User entered '04 Nov 2020 00:08'	System	04 Nov 2020 05:08:27
	System	04 Nov 2020 05:08:27

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:11:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:58:53
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 00:10:13

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '4 Nov 2020'	Yulexis Amestoy (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Yulexis Amestoy (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	04 Nov 2020 17:44:08

US3352424

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:53
User entered 'I'	System	04 Nov 2020 17:44:08

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:44:55

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:44:55

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Nov 2020 20:44:55

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:44:55

US3352424

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:45:05

US3352424

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:50
User entered 'I'	System	10 Nov 2020 20:45:05

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:19:15

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:19:15

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 20:19:15

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:19:15

US3352424

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:19:20

US3352424

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:16
User entered 'I'	System	19 Nov 2020 20:19:20

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:14

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Nov 2020'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:14

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:14

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'VISIT3'	System	25 Nov 2020 14:15:14

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Nov 2020'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '16:00'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered '24 Nov 2020 16:00'	System	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '36.9' C	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '85'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'bpm'	System	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'breaths/min'	System	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '117'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'mmHg'	System	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '82'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'mmHg'	System	25 Nov 2020 14:15:51

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30

US3352424

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:54

US3352424

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	Matthew Muniz (b) (4)	25 Nov 2020 14:15:54

US3352424

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	25 Nov 2020 14:16:07

US3352424

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '24 Nov 2020'	Matthew Muniz (b) (4)	25 Nov 2020 14:16:07

US3352424

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '16:25'	Matthew Muniz (b) (4)	25 Nov 2020 14:16:07

US3352424

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered '24 Nov 2020 16:25'	System	25 Nov 2020 14:16:07

US3352424

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	25 Nov 2020 14:15:06

US3352424

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:21:30
User entered 'I'	System	25 Nov 2020 14:15:06

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-22T00:18:05', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '68ef6b4a-b237-43c3-9c63-e2ebdebc70'	System	22 Nov 2020 05:29:33
User entered 'No (N)'	System	22 Nov 2020 05:29:33

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-22T00:18:29', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '68ef6b4a-b237-43c3-9c63-e2ebdebc70'	System	22 Nov 2020 05:29:33
User entered 'No (N)'	System	22 Nov 2020 05:29:33

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-22T00:18:36', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '68ef6b4a-b237-43c3-9c63-e2ebdebcdc70'	System	22 Nov 2020 05:29:33
User entered '22 Nov 2020 00:18:36'	System	22 Nov 2020 05:29:33

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-28T23:49:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fa967b7-7a0f-4ffe-8aab-efafa6c9a304'	System	29 Nov 2020 04:50:14
User entered 'No (N)'	System	29 Nov 2020 04:50:14

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-28T23:50:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fa967b7-7a0f-4ffe-8aab-efafa6c9a304'	System	29 Nov 2020 04:50:14
User entered 'No (N)'	System	29 Nov 2020 04:50:14

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-11-28T23:50:12', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6fa967b7-7a0f-4ffe-8aab-efafa6c9a304'	System	29 Nov 2020 04:50:14
User entered '28 Nov 2020 23:50:12'	System	29 Nov 2020 04:50:14

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-06T19:23:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4945b362-e7be-4198-82cd-e8e664753583'	System	07 Dec 2020 00:24:01
User entered 'No (N)'	System	07 Dec 2020 00:24:01

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-06T19:23:55', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4945b362-e7be-4198-82cd-e8e664753583'	System	07 Dec 2020 00:24:01
User entered 'No (N)'	System	07 Dec 2020 00:24:01

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-06T19:24:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '4945b362-e7be-4198-82cd-e8e664753583' User entered '06 Dec 2020 19:24:01'	System	07 Dec 2020 00:24:01
	System	07 Dec 2020 00:24:01

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-12T18:56:22', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '2276eefe-7812-4fa1-8e17-365da2d71ab7'	System	13 Dec 2020 00:02:36
User entered 'No (N)'	System	13 Dec 2020 00:02:36

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-12T18:57:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '2276eefe-7812-4fa1-8e17-365da2d71ab7' User entered 'No (N)'	System	13 Dec 2020 00:02:36

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-12T19:02:31', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '2276eefe-7812-4fa1-8e17-365da2d71ab7' User entered '12 Dec 2020 19:02:31'	System	13 Dec 2020 00:02:36
	System	13 Dec 2020 00:02:36

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-21T12:00:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8cbac007-cf9b-4292-9eb2-e5d41e909fe1' User entered 'No (N)'	System	21 Dec 2020 17:03:09
	System	21 Dec 2020 17:03:09

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-21T12:03:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8cbac007-cf9b-4292-9eb2-e5d41e909fe1'	System	21 Dec 2020 17:03:09
User entered 'No (N)'	System	21 Dec 2020 17:03:09

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-21T12:03:08', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '8cbac007-cf9b-4292-9eb2-e5d41e909fe1' User entered '21 Dec 2020 12:03:08'	System	21 Dec 2020 17:03:09
	System	21 Dec 2020 17:03:09

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-26T21:29:59', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e73578d6-4a78-4fec-a7a4-03a7adf83691' User entered 'No (N)'	System	27 Dec 2020 02:30:15
	System	27 Dec 2020 02:30:15

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-26T21:30:09', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e73578d6-4a78-4fec-a7a4-03a7adf83691' User entered 'No (N)'	System	27 Dec 2020 02:30:15
	System	27 Dec 2020 02:30:15

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2020-12-26T21:30:16', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'e73578d6-4a78-4fec-a7a4-03a7adf83691' User entered '26 Dec 2020 21:30:16'	System	27 Dec 2020 02:30:15
	System	27 Dec 2020 02:30:15

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-02T12:44:33', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd1042876-8ff1-4f33-9615-eb8bffb4f177'	System	02 Jan 2021 17:45:50
User entered 'No (N)'	System	02 Jan 2021 17:45:50

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-02T12:44:57', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd1042876-8ff1-4f33-9615-eb8bffb4f177'	System	02 Jan 2021 17:45:50
User entered 'No (N)'	System	02 Jan 2021 17:45:50

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-02T12:45:49', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd1042876-8ff1-4f33-9615-eb8bffb4f177'	System	02 Jan 2021 17:45:50
User entered '02 Jan 2021 12:45:49'	System	02 Jan 2021 17:45:50

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-10T21:35:18', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b1298ab-7092-4c2d-abbc-f719efc1cf8d' User entered 'No (N)'	System	11 Jan 2021 02:35:31
	System	11 Jan 2021 02:35:31

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-10T21:35:29', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b1298ab-7092-4c2d-abbc-f719efc1cf8d' User entered 'No (N)'	System	11 Jan 2021 02:35:31
	System	11 Jan 2021 02:35:31

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-10T21:35:34', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '3b1298ab-7092-4c2d-abbc-f719efc1cf8d' User entered '10 Jan 2021 21:35:34'	System	11 Jan 2021 02:35:31

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-16T15:22:23', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b4bb7573-f5d7-47a2-89de-e8dcbeda9ff0'	System	16 Jan 2021 20:23:43
User entered 'No (N)'	System	16 Jan 2021 20:23:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-16T15:23:24', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b4bb7573-f5d7-47a2-89de-e8dcbeda9ff0' User entered 'No (N)'	System	16 Jan 2021 20:23:43
	System	16 Jan 2021 20:23:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-16T15:23:43', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'b4bb7573-f5d7-47a2-89de-e8dcbeda9ff0' User entered '16 Jan 2021 15:23:43'	System	16 Jan 2021 20:23:43
	System	16 Jan 2021 20:23:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-23T21:22:01', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7d6b981-9efd-4ad3-8f5d-7f6c633ef037'	System	24 Jan 2021 02:22:06
User entered 'No (N)'	System	24 Jan 2021 02:22:06

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-23T21:21:54', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7d6b981-9efd-4ad3-8f5d-7f6c633ef037'	System	24 Jan 2021 02:22:06
User entered 'No (N)'	System	24 Jan 2021 02:22:06

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-23T21:22:10', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'f7d6b981-9efd-4ad3-8f5d-7f6c633ef037'	System	24 Jan 2021 02:22:06
User entered '23 Jan 2021 21:22:10'	System	24 Jan 2021 02:22:06

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-30T18:35:04', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6634d5f4-2d77-4475-ab2a-4e8d9fdc6005' User entered 'No (N)'	System	30 Jan 2021 23:35:16
	System	30 Jan 2021 23:35:16

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-30T18:35:13', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6634d5f4-2d77-4475-ab2a-4e8d9fdc6005'	System	30 Jan 2021 23:35:16
User entered 'No (N)'	System	30 Jan 2021 23:35:16

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-01-30T18:35:21', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6634d5f4-2d77-4475-ab2a-4e8d9fdc6005' User entered '30 Jan 2021 18:35:21'	System	30 Jan 2021 23:35:16
	System	30 Jan 2021 23:35:16

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-06T13:58:28', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '55d05f92-d905-4738-86a5-32d3dc6ee398' User entered 'No (N)'	System	06 Feb 2021 18:58:42
	System	06 Feb 2021 18:58:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-06T13:58:35', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '55d05f92-d905-4738-86a5-32d3dc6ee398'	System	06 Feb 2021 18:58:42
User entered 'No (N)'	System	06 Feb 2021 18:58:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-06T13:58:47', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '55d05f92-d905-4738-86a5-32d3dc6ee398' User entered '06 Feb 2021 13:58:47'	System	06 Feb 2021 18:58:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-14T14:13:40', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '10ce7305-a5a3-433f-9697-58e6cce2c2d9' User entered 'No (N)'	System	14 Feb 2021 19:13:44

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-14T14:13:45', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '10ce7305-a5a3-433f-9697-58e6cce2c2d9' User entered 'No (N)'	System	14 Feb 2021 19:13:44
	System	14 Feb 2021 19:13:44

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-14T14:13:50', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '10ce7305-a5a3-433f-9697-58e6cce2c2d9' User entered '14 Feb 2021 14:13:50'	System	14 Feb 2021 19:13:44
	System	14 Feb 2021 19:13:44

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-20T15:10:34', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0c3fdada-be92-47b8-8b50-3249b7ca2c25'	System	20 Feb 2021 20:10:37
User entered 'No (N)'	System	20 Feb 2021 20:10:37

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-20T15:10:38', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0c3fdada-be92-47b8-8b50-3249b7ca2c25'	System	20 Feb 2021 20:10:37
User entered 'No (N)'	System	20 Feb 2021 20:10:37

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-02-20T15:10:42', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '0c3fdada-be92-47b8-8b50-3249b7ca2c25' User entered '20 Feb 2021 15:10:42'	System	20 Feb 2021 20:10:37
	System	20 Feb 2021 20:10:37

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-01T10:41:28-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1119553c-5f4b-42a3-994b-15d46cdeb5b5'	System	01 Mar 2021 15:41:35
User entered 'No (N)'	System	01 Mar 2021 15:41:35

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-01T10:41:39-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1119553c-5f4b-42a3-994b-15d46cdeb5b5'	System	01 Mar 2021 15:41:35
User entered 'No (N)'	System	01 Mar 2021 15:41:35

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-01T10:41:43-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '1119553c-5f4b-42a3-994b-15d46cdeb5b5'	System	01 Mar 2021 15:41:35
User entered '01 Mar 2021 15:41:43'	System	01 Mar 2021 15:41:35

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-08T12:11:04-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a37336b2-8c2c-414b-8e37-031fb503eac4'	System	08 Mar 2021 17:19:22
User entered 'No (N)'	System	08 Mar 2021 17:19:22

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-08T12:11:13-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a37336b2-8c2c-414b-8e37-031fb503eac4'	System	08 Mar 2021 17:19:22
User entered 'No (N)'	System	08 Mar 2021 17:19:22

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-08T12:11:16-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'a37336b2-8c2c-414b-8e37-031fb503eac4' User entered '08 Mar 2021 12:11:16'	System	08 Mar 2021 17:19:22
	System	08 Mar 2021 17:19:22

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-15T12:38:32-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '26589a5f-bf75-401b-9d65-e96fbbb3a19e'	System	15 Mar 2021 16:38:49
User entered 'No (N)'	System	15 Mar 2021 16:38:49

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-15T12:38:41-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '26589a5f-bf75-401b-9d65-e96fbbb3a19e'	System	15 Mar 2021 16:38:49
User entered 'No (N)'	System	15 Mar 2021 16:38:49

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-15T12:38:46-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '26589a5f-bf75-401b-9d65-e96fbbb3a19e' User entered '15 Mar 2021 12:38:46'	System	15 Mar 2021 16:38:49
	System	15 Mar 2021 16:38:49

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-20T18:19:11-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533866f3-d6aa-439e-806c-381adb8575d6'	System	20 Mar 2021 22:19:23
User entered 'No (N)'	System	20 Mar 2021 22:19:23

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-20T18:19:15-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533866f3-d6aa-439e-806c-381adb8575d6'	System	20 Mar 2021 22:19:23
User entered 'No (N)'	System	20 Mar 2021 22:19:23

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-20T18:19:19-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '533866f3-d6aa-439e-806c-381adb8575d6' User entered '20 Mar 2021 18:19:19'	System	20 Mar 2021 22:19:23
	System	20 Mar 2021 22:19:23

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-27T14:06:23-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c3c1a652-008e-4170-ad8f-0b8b6093decd' User entered 'No (N)'	System	27 Mar 2021 18:06:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-27T14:06:33-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c3c1a652-008e-4170-ad8f-0b8b6093decd' User entered 'No (N)'	System	27 Mar 2021 18:06:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-27T14:06:37-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'c3c1a652-008e-4170-ad8f-0b8b6093decd' User entered '27 Mar 2021 14:06:37'	System	27 Mar 2021 18:06:42
	System	27 Mar 2021 18:06:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-03T23:18:57-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '58a301ac-b024-41c1-8565-93e8d05af587' User entered 'No (N)'	System	04 Apr 2021 03:19:08
	System	04 Apr 2021 03:19:08

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-03T23:19:03-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '58a301ac-b024-41c1-8565-93e8d05af587' User entered 'No (N)'	System	04 Apr 2021 03:19:08

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-03T23:19:06-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '58a301ac-b024-41c1-8565-93e8d05af587'	System	04 Apr 2021 03:19:08
User entered '03 Apr 2021 23:19:06'	System	04 Apr 2021 03:19:08

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-12T08:22:30-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7ae27d28-b80b-4590-9b99-8584d2758c95'	System	12 Apr 2021 12:22:43
User entered 'No (N)'	System	12 Apr 2021 12:22:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-12T08:22:35-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7ae27d28-b80b-4590-9b99-8584d2758c95'	System	12 Apr 2021 12:22:43
User entered 'No (N)'	System	12 Apr 2021 12:22:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-12T08:22:39-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '7ae27d28-b80b-4590-9b99-8584d2758c95'	System	12 Apr 2021 12:22:43
User entered '12 Apr 2021 08:22:39'	System	12 Apr 2021 12:22:43

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-17T23:21:48-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '09f50f4f-c640-4d58-8436-d8ec43afdf83' User entered 'No (N)'	System	18 Apr 2021 03:22:11
	System	18 Apr 2021 03:22:11

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-17T23:21:58-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '09f50f4f-c640-4d58-8436-d8ec43afdf83'	System	18 Apr 2021 03:22:11
User entered 'No (N)'	System	18 Apr 2021 03:22:11

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-17T23:22:07-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '09f50f4f-c640-4d58-8436-d8ec43afdf83'	System	18 Apr 2021 03:22:11
User entered '17 Apr 2021 23:22:07'	System	18 Apr 2021 03:22:11

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-25T20:01:59-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c231682-56ed-4898-91aa-de4759d593b2'	System	26 Apr 2021 00:02:24
User entered 'No (N)'	System	26 Apr 2021 00:02:24

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-25T20:02:08-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c231682-56ed-4898-91aa-de4759d593b2'	System	26 Apr 2021 00:02:24
User entered 'No (N)'	System	26 Apr 2021 00:02:24

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-04-25T20:02:20-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '9c231682-56ed-4898-91aa-de4759d593b2'	System	26 Apr 2021 00:02:24
User entered '25 Apr 2021 20:02:20'	System	26 Apr 2021 00:02:24

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-05-01T13:07:16-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd863f677-e312-4fb0-9619-864b1bba931a' User entered 'No (N)'	System	01 May 2021 17:07:42
	System	01 May 2021 17:07:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

Have you been exposed to someone with 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 (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-05-01T13:07:23-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd863f677-e312-4fb0-9619-864b1bba931a' User entered 'No (N)'	System	01 May 2021 17:07:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-05-01T13:07:28-04:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: 'd863f677-e312-4fb0-9619-864b1bba931a'	System	01 May 2021 17:07:42
User entered '01 May 2021 13:07:28'	System	01 May 2021 17:07:42

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:42:27

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:42:27
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:42:27

US3352424

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:14

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)	26 Apr 2021 05:42:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-01T10:42:19-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6e2fff2b-f255-43af-98c6-3704cde76985'	System	01 Mar 2021 15:44:26
User entered 'No (N)'	System	01 Mar 2021 15:44:26

US3352424

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:42:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ADA538D-8969-4566-9990-8860CA2117D7)', Time: '2021-03-01T10:44:33-05:00', User OID: 'PatientReportedOutcome (US3352424)', ODM File OID: '6e2fff2b-f255-43af-98c6-3704cde76985' User entered '01 Mar 2021 15:44:33'	System	01 Mar 2021 15:44:26
	System	01 Mar 2021 15:44:26

US3352424

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 19JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:19:21
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 19JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'DATA HAS BEEN ENTERED' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:26:49
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 19JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:28:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:51:55

US3352424

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '21 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 19:51:55

US3352424

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Dec 2020 19:51:55

US3352424

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:51:55

US3352424

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:51:59

US3352424

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:43:19
User entered 'I'	System	21 Dec 2020 19:51:59

US3352424

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:40:25

US3352424

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 06:41:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:26:14
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 12:32:37
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 16:40:25

US3352424

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Jan 2021 16:40:25

US3352424

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:40:25

US3352424

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:40:30

US3352424

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:52
User entered 'I'	System	25 Jan 2021 16:40:30

US3352424

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 16:54:54

US3352424

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 16:54:54

US3352424

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 16:54:54

US3352424

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 16:54:54

US3352424

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 16:54:58

US3352424

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:29
User entered 'I'	System	23 Feb 2021 16:54:58

US3352424

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 17:09:34

US3352424

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 17:09:34

US3352424

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Mar 2021 17:09:34

US3352424

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 17:09:34

US3352424

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 17:02:22

US3352424

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:11:21
User entered 'I'	System	26 Mar 2021 17:02:22

US3352424

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:39:37

US3352424

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:39:37

US3352424

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Apr 2021 20:39:37

US3352424

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	26 Apr 2021 20:39:37

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:35'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 15:35'	System	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '37.0' C	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '96'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '16'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '125'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '82'	(b) (4), (b) (6)	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 20:40:23

US3352424

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 20:39:43

US3352424

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 20:39:43

US3352424

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:39:53

US3352424

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:39:53

US3352424

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '15:48'	(b) (4), (b) (6)	26 Apr 2021 20:39:53

US3352424

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 15:48'	System	26 Apr 2021 20:39:53

US3352424

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:39:57

US3352424

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 20:39:57

US3352424

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:28:53

US3352424

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '19 Jan 2021' reason for change: Data Entry Error	Matthew Muniz (b) (4)	26 Feb 2021 19:30:50
User entered '26 Feb 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:28:53

US3352424

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	26 Feb 2021 19:28:53

US3352424

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'UNBLND_DECIDE'	System	26 Feb 2021 19:28:53

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '19 Jan 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:57:59

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:57:59

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '19 Jan 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Placebo (Placebo)'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Placebo (Placebo)'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Placebo (Placebo)'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '1'	System	26 Feb 2021 19:29:21

US3352424

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'I'	System	26 Feb 2021 19:29:21

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered empty.	System	26 Feb 2021 19:32:13
DataPoint set to visible.	System	26 Feb 2021 19:29:21

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered empty.	System	26 Feb 2021 19:32:13
DataPoint set to visible.	System	26 Feb 2021 19:29:21

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '18 Feb 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '13:45'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '18 Feb 2021 13:45'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '36.9' C	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '89'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'bpm'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '16'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'breaths/min'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '111'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'mmHg'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '71'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'mmHg'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered empty.	System	26 Feb 2021 19:32:13
DataPoint set to visible.	System	26 Feb 2021 19:29:21

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '18 Feb 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '14:45'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '18 Feb 2021 14:45'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '36.8' C	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '92'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'bpm'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '16'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'breaths/min'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '121'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'mmHg'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '80'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:13

US3352424

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'mmHg'	System	26 Feb 2021 19:32:13

US3352424

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Feb 2021 19:32:24

US3352424

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:32:24

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered empty.	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'mRNA-1273'	System	26 Feb 2021 19:34:07
DataPoint set to visible.	System	26 Feb 2021 19:29:21

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 18FEB2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:45:27
Query 'Per IRT, Subject had Open Label Day1 Treatment on 18FEB2021. Please review and reconcile. ' answered with 'data updated ' (Site from DM).	Matthew Muniz (b) (4)	09 Apr 2021 14:04:21
User entered '18 Feb 2021' reason for change: Data Entry Error	Matthew Muniz (b) (4)	09 Apr 2021 14:04:04
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 18FEB2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:26:17
User entered '26 Feb 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '14:23'	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '18 Feb 2021 14:23'	System	09 Apr 2021 14:04:04
User entered '26 Feb 2021 14:23'	System	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Right Arm (RIGHT ARM)'	Matthew Muniz (b) (4)	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'ONCE'	System	26 Feb 2021 19:34:07

US3352424

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 19:34:07

US3352424

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:30:38

US3352424

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 19:30:50
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 19:30:38
User entered '19 Jan 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:30:38

US3352424

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '15:56'	Matthew Muniz (b) (4)	26 Feb 2021 19:30:38

US3352424

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '19 Jan 2021 15:56'	System	26 Feb 2021 19:30:38

US3352424

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:35:04

US3352424

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '19 Jan 2021'	Matthew Muniz (b) (4)	26 Feb 2021 19:35:04

US3352424

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '15:51'	Matthew Muniz (b) (4)	26 Feb 2021 19:35:04

US3352424

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered '19 Jan 2021 15:51'	System	26 Feb 2021 19:35:04

US3352424

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Feb 2021 19:35:35

US3352424

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:16
User entered 'I'	System	26 Feb 2021 19:35:35

US3352424

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:36:54

US3352424

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 06:46:05
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'corrected to actual date of contact' (Site from System).	Yulexis Amestoy (b) (4)	04 Mar 2021 19:43:07
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 19:42:11
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 14:37:06
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Mar 2021 14:36:54
User entered '25 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 14:36:54

US3352424

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Mar 2021 14:36:54

US3352424

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:36:54

US3352424

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:37:32

US3352424

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User entered 'I'	System	01 Mar 2021 14:37:32

US3352424

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:52:58
User entered 'I'	System	01 Mar 2021 14:37:32
DataPoint set to visible.	System	01 Mar 2021 14:37:32

US3352424

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Mar 2021 18:51:20

US3352424

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 09:37:22
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'protocol deviation has been filed for visit out of window' (Site from System).	(b) (4), (b) (6)	20 Mar 2021 18:52:07
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	20 Mar 2021 18:51:20
User entered '20 Mar 2021'	(b) (4), (b) (6)	20 Mar 2021 18:51:20

US3352424

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Mar 2021 18:51:20

US3352424

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'OLD29'	System	20 Mar 2021 18:51:20

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '20 Mar 2021'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '12:44'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered '20 Mar 2021 12:44'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '36.9' C	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '96'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'bpm'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '14'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'breaths/min'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '118'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'mmHg'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '81'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'mmHg'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '20 Mar 2021'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '13:46'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered '20 Mar 2021 13:46'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '36.8' C	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '92'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'bpm'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '15'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'breaths/min'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '122'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'mmHg'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '81'	(b) (4), (b) (6)	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'mmHg'	System	20 Mar 2021 18:52:55

US3352424

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Mar 2021 18:53:00

US3352424

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	20 Mar 2021 18:53:00

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'mRNA-1273'	System	20 Mar 2021 18:53:21
DataPoint set to visible.	System	01 Mar 2021 14:37:32

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '20 Mar 2021'	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '13:16'	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered '20 Mar 2021 13:16'	System	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'ONCE'	System	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'INTRAMUSCULAR'	System	20 Mar 2021 18:53:21

US3352424

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Mar 2021 18:53:27

US3352424

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:25
User entered 'I'	System	20 Mar 2021 18:53:27

US3352424

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 17:15:05

US3352424

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered '29 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 17:15:05

US3352424

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Mar 2021 17:15:05

US3352424

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 17:15:05

US3352424

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 17:20:42

US3352424

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 17:20:42

US3352424

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:38:42

US3352424

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:38:42

US3352424

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Apr 2021 20:38:42

US3352424

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	26 Apr 2021 20:38:42

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '15:35'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 15:35'	System	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '37.0' C	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '96'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '16'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '125'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '82'	(b) (4), (b) (6)	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 20:39:13

US3352424

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 20:38:48

US3352424

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 20:38:48

US3352424

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 20:39:25

US3352424

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:39:25

US3352424

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '15:48'	(b) (4), (b) (6)	26 Apr 2021 20:39:25

US3352424

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 15:48'	System	26 Apr 2021 20:39:25

US3352424

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:11:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Please complete the Concomitant Procedures Summary as "yes", because the subject had a Chest X-Ray, and a 12-lead EKG done while in the hospital on 17 Oct 2020. The subject also had an Echocardiogram with doppler on 18 Oct 2020. See Hospital records starting on page 19. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:34:14
Query 'Please complete the Concomitant Procedures Summary as "yes", because the subject had a Chest X-Ray, and a 12-lead EKG done while in the hospital on 17 Oct 2020. The subject also had an Echocardiogram with doppler on 18 Oct 2020. See Hospital records starting on page 19. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Dec 2020 14:04:34
User opened query 'Please complete the Concomitant Procedures Summary as "yes", because the subject had a Chest X-Ray, and a 12-lead EKG done while in the hospital on 17 Oct 2020. The subject also had an Echocardiogram with doppler on 18 Oct 2020. See Hospital records starting on page 19. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:26:08
Query 'Please complete the Concomitant Procedures Summary as "yes", because the subject had a Chest X-Ray done while in the hospital on 17 Oct 2020. See Hospital records page 20. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:15:06
User opened query 'Please complete the Concomitant Procedures Summary as "yes", because the subject had a Chest X-Ray done while in the hospital on 17 Oct 2020. See Hospital records page 20. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:14:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 01:42:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:37:02
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:25:38
User entered	System	22 Oct 2020 17:25:35
'USA-US066-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 17:25:35

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 18:59:53
User closed query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:11:47
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 21:10:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 21:10:28
Data point term sent to Coder	System	29 Dec 2020 21:09:37
Query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 21:08:51
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 21:08:44
Coding entries removed.	(b) (4), (b) (6)	29 Dec 2020 21:08:44
User entered 'SINUS TACHYCARDIA' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 21:08:44
User opened query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:39:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 19:50:39
Data point term sent to Coder	System	21 Oct 2020 19:49:51
User entered 'TACHYCARDIA'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 19:53:01
User entered 'No (N)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:53:01
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 19:52:42
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 19:52:42
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 19:52:42
User entered '18 Oct 2020' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:52:42
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 19:49:45
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 18:59:49
	(b) (4), (b) (6)	31 Dec 2020 18:59:46
Query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' answered with 'Updated on source.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 21:08:24
	(b) (4), (b) (6)	02 Dec 2020 20:38:42
DataPoint Verified.		02 Dec 2020 20:38:26
User opened query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' (Site from CRA). DataPoint Un-verified.		02 Dec 2020 19:48:22
	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:18:04
User entered 'Grade 4 (Grade 4)' reason for change: New Information	(b) (4)	17 Nov 2020 19:18:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
Query 'Per source, subject was in the ER for 24 hours (not inpatient hospitalization); this does not meet criteria for serious. Please verify and update as needed.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:34:14
User opened query 'Per source, subject was in the ER for 24 hours (not inpatient hospitalization); this does not meet criteria for serious. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:32:23
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
Query 'Per source, subject was in the ER for 24 hours (not inpatient hospitalization); this does not meet criteria for serious. Please verify and update as needed.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:34:12
User opened query 'Per source, subject was in the ER for 24 hours (not inpatient hospitalization); this does not meet criteria for serious. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:32:56
User entered 'I'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:52:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:52:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:52:42
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:49:45
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR - RQ: Site's response noted. However, CM #10 are being taken to prevent further episodes of Tachycardia and not directly to treat this AE. Please seek assistance of your local CRA before answering this query. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 15:32:04
Query 'Per DM CLR - RQ: Site's response noted. However, CM #10 are being taken to prevent further episodes of Tachycardia and not directly to treat this AE. Please seek assistance of your local CRA before answering this query. ' answered with 'con meds updated please refer to con med page ' (Site from DM).	Matthew Muniz (b) (4)	12 Apr 2021 16:17:55
User opened query 'Per DM CLR - RQ: Site's response noted. However, CM #10 are being taken to prevent further episodes of Tachycardia and not directly to treat this AE. Please seek assistance of your local CRA before answering this query. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:42:50
User closed query 'Per DM CLR - RQ: Site's response noted. However, METOPROLOL was started on 23OCT2020 while this AE ended on 18OCT2020. Therefore, this AE was already resolved when Metoprolol was started. Please review and add a Con Medication as appropriate or update response to this field. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:11:19
Query 'Per DM CLR - RQ: Site's response noted. However, METOPROLOL was started on 23OCT2020 while this AE ended on 18OCT2020. Therefore, this AE was already resolved when Metoprolol was started. Please review and add a Con Medication as appropriate or update response to this field. ' answered with 'Data is correct, subject is taking this medication for hypertension and tachycardia.' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 16:42:49

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Concomitant Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, METOPROLOL was started on 23OCT2020 while this AE ended on 18OCT2020. Therefore, this AE was already resolved when Metoprolol was started. Please review and add a Con Medication as appropriate or update response to this field. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:31:31
User closed query 'PER CDM Requery-Response noted,however,METROPROLOL start date 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020 which is not possible.Kindly consider to verify and update data accordingly else clarify..Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:01:46
Query 'PER CDM Requery-Response noted,however,METROPROLOL start date 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020 which is not possible.Kindly consider to verify and update data accordingly else clarify..Thank you.' answered with 'Per subject started on METROPROLOL post hospital discharge by cardiologist. ' (Site from DM).	Wanda Delgado (b) (4)	23 Nov 2020 14:16:11
User opened query 'PER CDM Requery-Response noted,however,METROPROLOL start date 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020 which is not possible.Kindly consider to verify and update data accordingly else clarify..Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:22:47
User closed query ' PER CDM Requery-Response noted,however,METROPROLOL WAS TAKEN on 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020.Kindly consider to verify and update data accordingly else clarify..Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:22:47
Query ' PER CDM Requery-Response noted,however,METROPROLOL WAS TAKEN on 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020.Kindly consider to verify and update data accordingly else clarify..Thank you.' answered with 'Metoprolol is taken to control the hypertension and tachycardia. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 16:09:16

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query ' PER CDM Requery-Response noted,however,METROPROLOL WAS TAKEN on 23 oct after Ae 'TACHYCARDIA' end date 18 oct 2020.Kindly consider to verify and update data accordingly else clarify..Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:58:15
User closed query 'PER CDM-Concomitant Medicationis cjecked,however,no cm is recorded with corresponding ae on cm page.Kindly consider to verify and update data appropriately.Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:58:15
Query 'PER CDM-Concomitant Medicationis cjecked,however,no cm is recorded with corresponding ae on cm page.Kindly consider to verify and update data appropriately.Thank you.' answered with 'METROPROLOL WAS TAKEN AND ENTERED IN EDC.' (Site from DM).	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 14:51:44
User opened query 'PER CDM-Concomitant Medicationis cjecked,however,no cm is recorded with corresponding ae on cm page.Kindly consider to verify and update data appropriately.Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:43:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query ' Per DM CLR Requery-Response noted as 'Data updated' ,however,there is no Conmed Procedure recorded with matching AE indication as 'SINUS TACHYCARDIA' .Kindly consider to verify and update data accordingly else please clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:17:59
Query ' Per DM CLR Requery-Response noted as 'Data updated' ,however,there is no Conmed Procedure recorded with matching AE indication as 'SINUS TACHYCARDIA' .Kindly consider to verify and update data accordingly else please clarify.' answered with 'entered in error, data updated' (Site from DM).	Matthew Muniz (b) (4)	12 Mar 2021 21:11:54
DataPoint Un-verified.	Matthew Muniz (b) (4)	12 Mar 2021 21:11:33
User entered '0' reason for change: Data Entry Error	Matthew Muniz (b) (4)	12 Mar 2021 21:11:33
User opened query ' Per DM CLR Requery-Response noted as 'Data updated' ,however,there is no Conmed Procedure recorded with matching AE indication as 'SINUS TACHYCARDIA' .Kindly consider to verify and update data accordingly else please clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:19:31
Query ' Per DM CLR Requery-Response noted as 'Data updated' ,however,there is no AE recorded with indication as 'SINUS TACHYCARDIA' on the Ae page.Kindly consider to verify and update data accordingly else please clarify.' canceled (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:18:38
User opened query ' Per DM CLR Requery-Response noted as 'Data updated' ,however,there is no AE recorded with indication as 'SINUS TACHYCARDIA' on the Ae page.Kindly consider to verify and update data accordingly else please clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:17:25

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:17:25
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 16:36:53
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:32:45
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 19:00:12
User closed query 'The subject had several procedures while in the hospital. Please check the box for this question. Additional queries for procedures were added to the AE summary eCRF, because the Concomitant Procedures Summary page is blank. Thank you.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 19:00:06
Query 'The subject had several procedures while in the hospital. Please check the box for this question. Additional queries for procedures were added to the AE summary eCRF, because the Concomitant Procedures Summary page is blank. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 14:04:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 14:04:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:48

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'The subject had several procedures while in the hospital. Please check the box for this question. Additional queries for procedures were added to the AE summary eCRF, because the Concomitant Procedures Summary page is blank. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:28:56
	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:49:45
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: SAE Narrative = RECENT LABORATORY RESULTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:05:58
Query 'Per DM CLR: SAE Narrative = RECENT LABORATORY RESULTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Data was updated' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 16:43:09
User opened query 'Per DM CLR: SAE Narrative = RECENT LABORATORY RESULTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:32:24
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:24:44
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:24:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:24:39
User closed query 'PV Query: Please provide date of vitals (BP, HR) that were reported.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:24:34

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent. ' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:52:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'DURING HOSPITAL ADMISSION SUBJECT HAD A SARS-COV-2 TEST DONE ON 18OCT2020 WITH A NEGATIVE RESULT.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:21:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'SODIUM 132 MEQ/L COLLECTED ON 17OCT2020 AND POTASSIUM 2.9 MEG/L ALSO COLLECTED ON 17OCT2020.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 14:57:17
Query 'PV Query: Please provide date of vitals (BP, HR) that were reported.' answered with 'Date of vitals reported was on the same date documented in the narrative of 17OCT2020.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 13:47:20
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:44:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:44:25

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:44:15
User opened query 'PV Query: Please provide date of vitals (BP, HR) that were reported.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:44:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 19:52:42
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 19:52:42
User entered 'Subject reported today going to the ER Rosaidaliz Carreira on Saturday 10/17/20 at 16:00 after having elevated blood pressure and tachycardia. He was told by the ER physician that his potassium was low . Subject reported that he was given potassium and IV fluids and finally discharged Sunday at approximate 19:00. Today he reports feeling well and denies any other health changes. Upon further interview with subject he reports starting new treatment for hyperlipidemia and hypertension 10/05/2020 based on recent laboratory results and follow up with his primary doctor.	(b) (4) (b) (4)	21 Oct 2020 19:52:42
Vital signs before dosing B/P 138/ 89, HR 97. 30 minutes post dose B/P 127/86 , HR 94.		
Pending to review medical records at this time. In view of the preliminary information that we have it seems that event of tachycardia and Hypertension is not related to study product instead from preexisting conditions not diagnosed prior to dosing.' reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 19:49:45
User entered empty.	Rosaidaliz Carreira (b) (4)	(b) (4) 21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:16
User entered 'USA-US066-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	22 Oct 2020 17:26:12

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:23:33
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 17:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 17:08:39
Data point term sent to Coder	System	09 Mar 2021 17:08:00
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 17:07:46
DataPoint Un-verified.	Wanda Delgado (b) (4)	09 Mar 2021 17:07:36
Coding entries removed.	Wanda Delgado (b) (4)	09 Mar 2021 17:07:36
User entered 'worsening of HYPERTENSION' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:07:36
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 11:32:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:55:40
Data point term sent to Coder	System	21 Oct 2020 19:55:07
User entered 'HYPERTENSION'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:46:44
User closed query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please reconcile source and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:46:43
Query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please reconcile source and EDC. Thank you.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:10:35
User entered 'Grade 4 (Grade 4)' reason for change:	(b) (4), (b) (6)	29 Dec 2020 21:10:26
Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 20:30:25
User opened query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please reconcile source and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:34:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:54:35
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rosaidaliz Carreira (b) (4)	(b) (4)

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'I'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'I'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered 'Subject reported today going to the ER on Saturday 10/17/20 at 16:00 after having elevated blood pressure and tachycardia. He was told by the ER physician that his potassium was low . Subject reported that he was given potassium and IV fluids and finally discharged Sunday at approximate 19:00. Today he reports feeling well and denies any other health changes. Upon further interview with subject he reports starting new treatment for hyperlipidemia and hypertension 10/05/2020 based on recent laboratory results and follow up with his primary doctor.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35

Vital signs before dosing B/P 138/ 89, HR 97.
30 minutes post dose B/P 127/86 , HR 94.

Pending to review medical records at this time. In view of the preliminary information that we have it seems that event of tachycardia and Hypertension is not related to study product instead from preexisting conditions not diagnosed prior to dosing.'

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 19:54:35

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:28:17
User entered 'USA-US066-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	18 Nov 2020 17:28:13

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:57:50
Data point term sent to Coder	System	17 Nov 2020 17:57:05
User entered 'HYPOKALEMIA'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:33:24
User closed query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please update the source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:33:22
Query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please update the source. Thank you.' answered with 'Updated in source' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:12:26
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 20:39:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User opened query 'Source document notes Grade 4 (the description on the source is blank and needs to be added). Please update the source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:32:18
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'I'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #12 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:23:49
Query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #12 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 17:08:18
User entered '0' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:08:10
User opened query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #12 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 11:32:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 13:59:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 13:59:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '1' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:08:10
User closed query 'Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly cpnsider to resolve and update data appropriately else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:52:46
Query 'Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly cpnsider to resolve and update data appropriately else clarify.Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:00:03
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 13:59:58
User entered '0' reason for change: Data Entry Error		30 Dec 2020 13:59:58
DataPoint Verified.		02 Dec 2020 20:39:19
DataPoint Un-verified.		02 Dec 2020 20:39:12
DataPoint Verified.		02 Dec 2020 20:38:26
User opened query 'Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly cpnsider to resolve and update data appropriately else clarify.Thank you.' (Site from DM).		25 Nov 2020 13:38:15
User entered '1'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 17:56:18
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 18:56:25
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 18:56:25
User entered 'SUBJECT REPORTED TODAY GOING TO THE ER ON SATURDAY 10/17/20 AT 16:00 AFTER HAVING ELEVATED BLOOD PRESSURE AND TACHYCARDIA. HE WAS TOLD BY THE ER PHYSICIAN THAT HIS POTASSIUM WAS LOW . SUBJECT REPORTED THAT HE WAS GIVEN POTASSIUM AND IV FLUIDS AND FINALLY DISCHARGED SUNDAY AT APPROXIMATE 19:00. TODAY HE REPORTS FEELING WELL AND DENIES ANY OTHER HEALTH CHANGES. UPON FURTHER INTERVIEW WITH SUBJECT HE REPORTS STARTING NEW TREATMENT FOR HYPERLIPIDEMIA AND HYPERTENSION 10/05/2020 BASED ON RECENT LABORATORY RESULTS AND FOLLOW UP WITH HIS PRIMARY DOCTOR.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 18:56:25
VITAL SIGNS BEFORE DOSING B/P 138/ 89, HR 97. 30 MINUTES POST DOSE B/P 127/86 , HR 94.		
PENDING TO REVIEW MEDICAL RECORDS AT THIS TIME. IN VIEW OF THE PRELIMINARY INFORMATION THAT WE HAVE IT SEEMS THAT EVENT OF TACHYCARDIA AND HYPERTENSION IS NOT RELATED TO STUDY PRODUCT INSTEAD FROM PREEXISTING CONDITIONS NOT DIAGNOSED PRIOR TO DOSING.' reason for change: Data Entry Error		

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 17:56:18
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
Reviewed for Safety.		18 Nov 2020 17:28:51
User entered 'USA-US066-2020-mRNA-1273-P301000002'		18 Nov 2020 17:28:46

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:15:53
Data point term sent to Coder	System	17 Nov 2020 19:14:29
User entered 'HYPONATREMIA'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:48:48
User closed query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:48:45
Query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:17:32
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 20:39:26
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User opened query 'While Grade 4 has been entered, Grade 4 is blank on your source document worksheet. Please update the source and/or EDC as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:35:16
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'I'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #13 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:24:01
Query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #13 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	09 Mar 2021 17:08:48
User entered '0' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:08:39
User opened query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #13 was given for this AE. If yes, please review and update this field and ensure that the CM indication is also updated. Verify and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 11:33:10
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:00:27
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:00:27
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '1' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:08:39
User closed query ' Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly consider to resolve and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:53:04
Query ' Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly consider to resolve and update data appropriately else clarify.Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:00:33
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:00:27
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:00:27
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User opened query ' Per CDM-Concomitant Medication is checked,however,no corresponding conmed is recorded with matching ae indication .Kindly consider to resolve and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:40:04
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:38:26
User entered 'SUBJECT REPORTED TODAY GOING TO THE ER ON SATURDAY 10/17/20 AT 16:00 AFTER HAVING ELEVATED BLOOD PRESSURE AND TACHYCARDIA. HE WAS TOLD BY THE ER PHYSICIAN THAT HIS POTASSIUM WAS LOW . SUBJECT REPORTED THAT HE WAS GIVEN POTASSIUM AND IV FLUIDS AND FINALLY DISCHARGED SUNDAY AT APPROXIMATE 19:00. TODAY HE REPORTS FEELING WELL AND DENIES ANY OTHER HEALTH CHANGES. UPON FURTHER INTERVIEW WITH SUBJECT HE REPORTS STARTING NEW TREATMENT FOR HYPERLIPIDEMIA AND HYPERTENSION 10/05/2020 BASED ON RECENT LABORATORY RESULTS AND FOLLOW UP WITH HIS PRIMARY DOCTOR.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:14:08
VITAL SIGNS BEFORE DOSING B/P 138/ 89, HR 97. 30 MINUTES POST DOSE B/P 127/86 , HR 94.		
PENDING TO REVIEW MEDICAL RECORDS AT THIS TIME. IN VIEW OF THE PRELIMINARY INFORMATION THAT WE HAVE IT SEEMS THAT EVENT OF TACHYCARDIA AND HYPERTENSION IS NOT RELATED TO STUDY PRODUCT INSTEAD FROM PREEXISTING CONDITIONS NOT DIAGNOSED PRIOR TO DOSING.'		

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 19:14:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 23:07:59
User closed query 'Per ETRTR: Please consider adding Medication dosed during Hospitalization for SAE "Tachycardia" if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 23:07:35
Query 'Per ETRTR: Please consider adding Medication dosed during Hospitalization for SAE "Tachycardia" if applicable, thanks.' answered with 'data updated in edc' (Site from CRA).	Matthew Muniz (b) (4)	29 Oct 2020 20:23:25
User opened query 'Per ETRTR: Please consider adding Medication dosed during Hospitalization for SAE "Tachycardia" if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 21:54:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:37:33

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:37:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:37:46
Data point term sent to Coder	System	24 Sep 2020 21:39:04
User entered 'SEROQUEL (Quetiapine)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'DEPRESSION'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '200'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'AT BEDTIME'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:38:51

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:28:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:28:41
Data point term sent to Coder	System	24 Sep 2020 21:40:05
User entered 'DEPAKOTE (Sodium valproate)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'BIPOLAR'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '125'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'UN UNK 2015'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 21:39:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TERAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:56:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:56:44
Data point term sent to Coder User entered 'TERAZOSIN'	System Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 19:56:14 21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERTENSION'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'I'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '13 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:26:00
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'Subject is still taking medication to treat hypertension.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:15:49
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:59:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:56:08

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: GEMFIBROZIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:59:49
Data point term sent to Coder	System	21 Oct 2020 19:58:23
User entered 'GEMFIBROZIL'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
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)	31 Dec 2020 06:09:51
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 'updated.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:16:38
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)	16 Dec 2020 03:57:42
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERLIPIDEMIA'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '600'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:57:35

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE, PRODUCTSYNONYM: CLORTALIDONA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:03:45
Data point term sent to Coder	System	21 Oct 2020 20:02:34
User entered 'CLORTALIDONA'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERTENSION'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '25'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User entered '1'	System	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User entered '1'	System	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:58
User entered '804 (804)'	System	21 Oct 2020 20:02:15

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
Data point term sent to Coder	System	21 Oct 2020 20:03:35
User entered 'OMEPRAZOLE'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'GASTRO REFLUX PREVENTION'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '20'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:03:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
Data point term sent to Coder Coding entries removed.	System Matthew Muniz (b) (4)	12 Apr 2021 16:16:23 12 Apr 2021 16:16:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:16:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:16:33
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Apr 2021 18:48:53 08 Apr 2021 18:48:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:21:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:21:27
Data point term sent to Coder	System	21 Oct 2020 20:04:36
User entered 'LOSARTAN POTASSIUM'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'HYPERTESION' reason for change: Data Entry Error	Matthew Muniz (b) (4)	12 Apr 2021 16:16:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:48:33
User entered 'HYPERTESION/tachycardia' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:48:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERTESION'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '25'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR-RQ: Response noted. However, no update was made. CM is still ongoing and AE has a stop date. Please provide necessary updates or provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:42:12
Query 'Per DM CLR-RQ: Response noted. However, no update was made. CM is still ongoing and AE has a stop date. Please provide necessary updates or provide clarification.' answered with 'updated ' (Site from DM).	Matthew Muniz (b) (4)	19 Feb 2021 14:53:51
DataPoint Un-verified.	Matthew Muniz (b) (4)	19 Feb 2021 14:53:30
User entered 'No (N)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Feb 2021 14:53:30
User opened query 'Per DM CLR-RQ: Response noted. However, no update was made. CM is still ongoing and AE has a stop date. Please provide necessary updates or provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 01:50:41
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 01:50:41
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:18:36
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:00:45

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Un-verified.	Matthew Muniz (b) (4)	19 Feb 2021 14:53:30
User entered '18 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Feb 2021 14:53:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:04:07
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User entered '1'	System	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User entered '1'	System	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:05
User entered '804 (804)'	System	21 Oct 2020 20:04:07

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, COMBINATIONS, ATC: HMG COA REDUCTASE INHIBITORS IN COMBINATION WITH OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE;SIMVASTATIN, PRODUCTSYNONYM: VYTORIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:23:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:23:50
Data point term sent to Coder DataPoint Un-verified.	System Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:22:42 17 Nov 2020 19:22:34
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:22:34
User entered 'VYTORIN' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:07:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:07:43
Data point term sent to Coder User entered 'SIMVASTATIN'	System Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 20:06:39 21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
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.	(b) (4), (b) (6)	31 Dec 2020 06:10:26
' (Site from DM). 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.	(b) (4), (b) (6)	30 Dec 2020 14:18:47
' answered with 'updated' (Site from DM). 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.	(b) (4), (b) (6)	16 Dec 2020 03:58:53
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERLIPIDEMIA'	Rosaidaliz Carreira (b) (4) (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 06:10:34
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:23:56
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:23:50
User entered '10/20' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:23:50
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:59:05
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '10'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:05:53

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:36:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:36:54
Data point term sent to Coder	System	29 Oct 2020 20:20:55
User entered 'aspirin'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'cardiovascular prophylaxis'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '81'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '05 Oct 2020'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Matthew Muniz (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:48:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:48:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Apr 2021 18:47:51 08 Apr 2021 18:47:05
User closed query 'Per Hospital Records on page 19, three medications were given to the subject while in the ER (aspirin, Potassium Bicarb-Citric Acid, and Sodium Chloride IV bolus). Please update your con med worksheet and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:36:22
Query 'Per Hospital Records on page 19, three medications were given to the subject while in the ER (aspirin, Potassium Bicarb-Citric Acid, and Sodium Chloride IV bolus). Please update your con med worksheet and EDC. Thank you.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	07 Dec 2020 20:00:17
User opened query 'Per Hospital Records on page 19, three medications were given to the subject while in the ER (aspirin, Potassium Bicarb-Citric Acid, and Sodium Chloride IV bolus). Please update your con med worksheet and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:13:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:06:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:06:21
Data point term sent to Coder	System	17 Nov 2020 14:52:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

2113 of 2344

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 14:51:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:24:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:24:45
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 20:24:00
User entered 'metoprolol er'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:47:05
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 14:51:13
User entered 'HYPERTENSION/TACHYCARDIA' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 14:51:13
DataPoint Verified.	Rosaidaliz Carreira (b) (4)	04 Nov 2020 02:37:41
User entered 'hypertension'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '50'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'mg (mg)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Please review Indication of Tachycardia as the start date of this medication is after the end date of this condition. Either update dates or remove indication of tachycardia. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 19:33:27
Query 'Per DM CLR: Please review Indication of Tachycardia as the start date of this medication is after the end date of this condition. Either update dates or remove indication of tachycardia. Else, clarify. ' answered with 'cc meds have been updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:47:18
User opened query 'Per DM CLR: Please review Indication of Tachycardia as the start date of this medication is after the end date of this condition. Either update dates or remove indication of tachycardia. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:55:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '23 Oct 2020'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '0'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:25:32
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'Subject is still taking medication to treat hypertension/tachycardia which has been added to medical history.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:25:02
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:00:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered empty.	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'No (N)'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:53:49
Data point term sent to Coder	System	07 Dec 2020 19:52:16
User entered 'aspirin'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'hypertension'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '162'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'mg (mg)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'once (ONCE)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User entered empty.	System	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User entered empty.	System	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:27
User entered empty.	System	07 Dec 2020 19:51:18

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: CITRIC ACID;POTASSIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:13:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:13:50
Data point term sent to Coder	System	09 Mar 2021 17:12:08
Coding entries removed.	Wanda Delgado (b) (4)	09 Mar 2021 17:11:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: CITRIC ACID;POTASSIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:29:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:29:47
Data point term sent to Coder	System	07 Dec 2020 19:55:21
User entered 'potassium bicarb citric acid'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'hypokalemia' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:11:25
User entered 'hypertension'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '40'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Other (OTHER)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'mEq'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'once (ONCE)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User entered empty.	System	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User entered empty.	System	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:36
User entered empty.	System	07 Dec 2020 19:55:06

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:26:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:59
Data point term sent to Coder	System	09 Mar 2021 17:14:12
Coding entries removed.	Wanda Delgado (b) (4)	09 Mar 2021 17:13:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:50:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:50:16
Data point term sent to Coder	System	07 Dec 2020 19:59:26
User entered 'sodium chloride'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Hyponatremia' reason for change: Data Entry Error	Wanda Delgado (b) (4)	09 Mar 2021 17:13:18
User entered 'hypertension'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '500'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:33:57
User entered 'Other (OTHER)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 19:32:55
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:34:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:33:57
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:46:30
User entered 'mc'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'once (ONCE)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Intravenous (INTRAVENOUS)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User entered empty.	System	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User entered empty.	System	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:43
User entered empty.	System	07 Dec 2020 19:58:48

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:57:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:57:58
Data point term sent to Coder	System	12 Apr 2021 16:16:24
User entered 'losartain potassium'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'sinus tachycardia'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '25'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'mg (mg)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'once daily (QD)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered empty.	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '05 Oct 2020'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '0'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered '18 Oct 2020'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'No (N)'	Matthew Muniz (b) (4)	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User entered '1'	System	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User entered '1'	System	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:47
User entered '804 (804)'	System	12 Apr 2021 16:15:40

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:11:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 21:11:46

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered '17 Oct 2020'	(b) (4), (b) (6)	30 Dec 2020 14:05:14

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Chest x-ray'	(b) (4), (b) (6)	30 Dec 2020 14:05:14

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	30 Dec 2020 14:05:14

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:05:14

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered '17 Oct 2020'	(b) (4), (b) (6)	30 Dec 2020 14:05:47

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered '12-lead ECG'	(b) (4), (b) (6)	30 Dec 2020 14:05:47

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	30 Dec 2020 14:05:47

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:36
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:05:47

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered '18 Oct 2020'	(b) (4), (b) (6)	30 Dec 2020 14:06:26

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Echocardiogram'	(b) (4), (b) (6)	30 Dec 2020 14:06:26

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	30 Dec 2020 14:06:26

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:06:26

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered '17 Oct 2020'	Wanda Delgado (b) (4)	09 Mar 2021 17:14:16

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Safety Labs'	Wanda Delgado (b) (4)	09 Mar 2021 17:14:16

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered 'Adverse Event (AE)'	Wanda Delgado (b) (4)	09 Mar 2021 17:14:16

US3352424

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:34:30
User entered empty.	Wanda Delgado (b) (4)	09 Mar 2021 17:14:16

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
User entered '22/Oct/2020 17:26'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
User entered '18/Nov/2020 17:29'	System	18 Nov 2020 17:29:59

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 17:29:59

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '21/Dec/2020 16:04'	System	21 Dec 2020 21:04:34

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:28:13
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 21:04:34

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '30/Dec/2020 15:28'	System	30 Dec 2020 15:29:06

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 15:29:06

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '10/Mar/2021 11:31'	System	10 Mar 2021 16:31:19

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 16:31:19

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'USA-US066-2020-MRNA-1273-P301000002'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'No (N)'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Howard'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'schwartz'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '7265 SHeridan Street SUite 210'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'Pembroke Pines'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered 'FL'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:26:50
User entered '33024'	System	22 Oct 2020 17:25:35

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:26:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:37
User entered 'US'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	15 Mar 2021 15:10:56
User entered '5'	System	10 Mar 2021 16:31:19
User entered '4'	System	30 Dec 2020 15:29:06
User entered '3'	System	21 Dec 2020 21:04:34
User entered '2'	System	18 Nov 2020 17:29:59
User entered '1'	System	22 Oct 2020 17:27:02

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:11:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered '15/Mar/2021 11:10'	System	15 Mar 2021 15:10:56

US3352424

Folder: SAE USA-US066-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:11:14

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:29
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:10:56