

US3352424 (Prod: Research Centers of America - ERG)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:40

All time stamps listed in this document are displayed in GMT

US3352424

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:40

[Participant ID](#)

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

US3352424

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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)	_____

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

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.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:40

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		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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 ☒

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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)

Generated On: 26 Nov 2020 11:01:40

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)

Generated On: 26 Nov 2020 11:01:40

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)	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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 OCT 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:01:40

Collection date (<i>dd MMM yyyy</i>)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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 ☐

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

		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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352424

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3352424

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

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

US3352424

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3352424

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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 ☒

Yes ☐

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

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: 26 Nov 2020 11:01:40

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 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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 11:01:40

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 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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

Patient Cloud Open Date & Time	26 DEC 2020 00:01
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Patient Cloud Close Date & Time	30 DEC 2020 23:59
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US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

02 JAN 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

09 JAN 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JAN 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

13 FEB 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 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: 26 Nov 2020 11:01:40

TIMEPOINT

DAY 159

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

06 MAR 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 11:01:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

17 APR 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

24 APR 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

01 MAY 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

08 MAY 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

15 MAY 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

22 MAY 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

29 MAY 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 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: 26 Nov 2020 11:01:40

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

12 JUN 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

19 JUN 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

21 AUG 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

28 AUG 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

04 SEP 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 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: 26 Nov 2020 11:01:40

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 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: 26 Nov 2020 11:01:40

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:01:40

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

07 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:01:40

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

Patient Cloud Open Date & Time	24 SEP 2022 00:01
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Patient Cloud Close Date & Time	28 SEP 2022 23:59
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US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 11:01:40

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="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: 26 Nov 2020 11:01:40

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

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 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: 26 Nov 2020 11:01:40

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 <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: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 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: 26 Nov 2020 11:01:40

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

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2022 00:01
Patient Cloud Close Date & Time	30 NOV 2022 23:59

US3352424

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352424

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:40

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)

Generated On: 26 Nov 2020 11:01:40

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	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"/>
Number of Days in ICU	
v6.020 DTW (1102)	332 of 1854

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

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 <input type="radio"/> 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)

Generated On: 26 Nov 2020 11:01:40

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
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Medically Attended AE Derived (CSA Programming Field Only)	1
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US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	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"/>
Number of Days in ICU	
v6.020 DTW (1102)	336 of 1854

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

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 <input type="radio"/> 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)

Generated On: 26 Nov 2020 11:01:40

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
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Medically Attended AE Derived (CSA Programming Field Only)	1
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US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

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"/>
Number of Days in ICU	
v6.020 DTW (1102)	340 of 1854

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

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 <input type="radio"/> 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)

Generated On: 26 Nov 2020 11:01:40

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
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Medically Attended AE Derived (CSA Programming Field Only)	1
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US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

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"/>
Number of Days in ICU	

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

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 <input type="radio"/> 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)

Generated On: 26 Nov 2020 11:01:40

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
Medically Attended AE Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

AEID	USA-US066-2020-MRNA-1273-P30 1000002
Adverse event	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"/>
Number of Days in ICU	
v6.020 DTW (1102)	348 of 1854

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

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 <input type="radio"/> 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 (5)

Generated On: 26 Nov 2020 11:01:40

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
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Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:40

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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	SEROQUEL (QUETIAPINE)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	AT BEDTIME Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	DEPAKOTE (SODIUM VALPROATE)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BIPOlar
Dose per administration	125
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

Name of Medication	TERAZOSIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	GEMFIBROZIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	600
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	CLORTALIDONA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

	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)		17 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	GASTRO REFLUX PREVENTION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	LOSARTAN POTASSIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTESION
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:40

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 (8)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	VYTORIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CARDIOVASCULAR PROPHYLAXIS
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
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"/>
<hr/>		
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)

Generated On: 26 Nov 2020 11:01:40

Name of Medication	METOPROLOL ER
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION/TACHYCARDIA
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:40

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3352424

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

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

Generated On: 26 Nov 2020 11:01:40

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)	2

US3352424

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:40

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)	2
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)

Generated On: 26 Nov 2020 11:01:40

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)	2
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

Audit

US3352424 (Prod: Research Centers of America - ERG)

US3352424

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3352424'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Sep 2020 19:14:08

US3352424

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Sep 2020 19:14:09

US3352424

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Sep 2020 21:28:34

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Sep 2020 19:14:10

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Age](#)

Audit	User	Time (GMT)
User entered '53'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '53'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

White

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:28:54

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:15:22

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Sep 2020 19:14:09

US3352424

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:15:44

US3352424

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:29:08

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4)	24 Sep 2020 21:36:39
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	(b) (4)	24 Sep 2020 21:36:39
Data point term sent to Coders System	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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 1973'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:27:41
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. ' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 18:56:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 1973'	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '1973'	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:41

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2010'	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:54

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2010'	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:36:22

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

Condition

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2009'	System	24 Sep 2020 21:37:15

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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
	(b) (4)	

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2010'	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:40:02

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - 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 'depression'	Matthew Muniz (b) (4)	27 Oct 2020 17:40:31
	(b) (4)	

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '2010'	System	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:40:31

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered '15:02'	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 15:02'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

Height (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Weight (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:29:52

US3352424

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:30:01

US3352424

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:30:01

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:40

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:30:37

US3352424

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	24 Sep 2020 21:30:55

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '115584'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Sep 2020 19:54:08

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:31:13

US3352424

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:40

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:40

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 21:32:27

US3352424

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

Was the physical examination performed?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:32:45

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:11'	(b) (4), (b) (6)	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 16:11'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 20:16:03

US3352424

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:33:13

US3352424

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:33:17

US3352424

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 21:33:17

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:42:37
User entered 'Yes (Y)'	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:42:37
User entered 'No (N)'	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:42:37
User entered '24 Sep 2020 16:42'	System	24 Sep 2020 20:42:37

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:03:41
User entered 'Yes (Y)'	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:03:41
User entered 'No (N)'	System	25 Sep 2020 00:03:41

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:01:22
User entered 'Yes (Y)'	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:01:22
User entered '98.0'	System	25 Sep 2020 20:01:22

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:00
User entered 'Yes (Y)'	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:00
User entered 'No (N)'	System	26 Sep 2020 17:32:00

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:57:08
User entered 'Yes (Y)'	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:57:08
User entered '99.4'	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:57:08
User entered 'No (N)'	System	27 Sep 2020 22:57:08

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:41:29
User entered 'Yes (Y)'	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:41:29
User entered '98.8'	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:41:29
User entered 'No (N)'	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:41:29
User entered '28 Sep 2020 16:41'	System	28 Sep 2020 20:41:29

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:12:34
User entered 'Yes (Y)'	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:12:34
User entered 'No (N)'	System	29 Sep 2020 21:12:34

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	30 Sep 2020 19:23:32
User entered 'Yes (Y)'	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	30 Sep 2020 19:23:32
User entered '98.3'	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	30 Sep 2020 19:23:32
User entered 'No (N)'	System	30 Sep 2020 19:23:32

US3352424

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:43:20
User entered 'None (1)'	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:43:20
User entered 'No (N)'	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:43:20
User entered 'No (N)'	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:43:20
User entered 'None (1)'	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 20:43:20
User entered '24 Sep 2020 16:43'	System	24 Sep 2020 20:43:20

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:05:51
User entered 'None (1)'	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:05:51
User entered 'No (N)'	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:05:51
User entered 'No (N)'	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:05:51
User entered 'None (1)'	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:05:51
User entered '24 Sep 2020 20:05'	System	25 Sep 2020 00:05:51

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:49
User entered 'None (1)'	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:49
User entered 'No (N)'	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:49
User entered 'No (N)'	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:32:49
User entered 'None (1)'	System	26 Sep 2020 17:32:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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-50fff51d303'	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: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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-50fff51d303'	System	27 Sep 2020 22:57:32
User entered 'No (N)'	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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-50fff51d303'	System	27 Sep 2020 22:57:32
User entered 'No (N)'	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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-50fff51d303'	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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-50fff51d303'	System	27 Sep 2020 22:57:32
User entered '27 Sep 2020 18:57'	System	27 Sep 2020 22:57:32

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:41:49
User entered '28 Sep 2020 16:41'	System	28 Sep 2020 20:41:49

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:13:28
User entered 'None (1)'	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:13:28
User entered 'No (N)'	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:13:28
User entered 'No (N)'	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:13:28
User entered 'None (1)'	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:13:28
User entered '29 Sep 2020 17:13'	System	29 Sep 2020 21:13:28

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	30 Sep 2020 19:24:00
User entered 'No (N)'	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	30 Sep 2020 19:24:00
User entered 'No (N)'	System	30 Sep 2020 19:24:00

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 00:07:24
User entered 'No interference with activity (1)'	System	25 Sep 2020 00:07:24

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'None (0)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'None (0)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'None (0)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'None (0)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'None (0)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 20:05:17
User entered 'No (N)'	System	25 Sep 2020 20:05:17

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:33:43
User entered 'None (0)'	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:33:43
User entered 'None (0)'	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:33:43
User entered 'None (0)'	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:33:43
User entered 'None (0)'	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:33:43
User entered 'No (N)'	System	26 Sep 2020 17:33:43

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'None (0)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'None (0)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'None (0)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'None (0)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'None (0)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 22:58:13
User entered 'No (N)'	System	27 Sep 2020 22:58:13

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'None (0)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'None (0)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'None (0)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'None (0)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'None (0)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered 'No (N)'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 20:42:29
User entered '28 Sep 2020 16:42'	System	28 Sep 2020 20:42:29

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 21:14:23
User entered 'None (0)'	System	29 Sep 2020 21:14:23

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Yulexis Amestoy (b) (4) (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	02 Oct 2020 13:52:39
	(b) (4)	

US3352424

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	02 Oct 2020 13:52:39

US3352424

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	02 Oct 2020 13:52:45

US3352424

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 13:52:45

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Yulexis Amestoy (b) (4) (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	08 Oct 2020 19:14:37

US3352424

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	08 Oct 2020 19:14:42

US3352424

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 19:14:42

US3352424

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:05:57

US3352424

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 21:06:00

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:29:56
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 02:26:29
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:21:03
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	27 Oct 2020 17:30:10
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	27 Oct 2020 17:30:10

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Temperature (xxx.x)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Route of measurement](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[If Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Temperature (xxx.x)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered 'Oral (Oral)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[If Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:30:02
User entered '97'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 17:31:19

US3352424

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If No, reason not given](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 15:51:44

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:38:35

US3352424

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 17:38:43

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:16:34
User entered 'Yes (Y)'	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:16:34
User entered 'No (N)'	System	27 Oct 2020 16:16:34

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:55:32
User entered 'Yes (Y)'	System	28 Oct 2020 01:55:32

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:01:30
User entered 'No (N)'	System	29 Oct 2020 00:01:30

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:00:59
User entered 'Yes (Y)'	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:00:59
User entered 'No (N)'	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:00:59
User entered '29 Oct 2020 22:00'	System	30 Oct 2020 02:00:59

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:49:04
User entered 'Yes (Y)'	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:49:04
User entered '98.6'	System	31 Oct 2020 04:49:04

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:15
User entered 'Yes (Y)'	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:15
User entered '98.3'	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:15
User entered '31 Oct 2020 21:22'	System	01 Nov 2020 01:22:15

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:12
User entered '98.1'	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:12
User entered '01 Nov 2020 19:09'	System	02 Nov 2020 00:09:12

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:33
User entered 'Yes (Y)'	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:33
User entered '97.6'	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:33
User entered 'No (N)'	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:33
User entered '02 Nov 2020 22:25'	System	03 Nov 2020 03:25:33

US3352424

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:17:20
User entered 'No (N)'	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:17:20
User entered 'No (N)'	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:17:20
User entered '27 Oct 2020 12:17'	System	27 Oct 2020 16:17:20

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:57:45
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:57:45
User entered 'No (N)'	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:57:45
User entered 'No (N)'	System	28 Oct 2020 01:57:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:02:45
User entered 'None (1)'	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:02:45
User entered 'No (N)'	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:02:45
User entered 'None (1)'	System	29 Oct 2020 00:02:45

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:01:40
User entered 'None (1)'	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:01:40
User entered 'No (N)'	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:01:40
User entered 'No (N)'	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:01:40
User entered 'None (1)'	System	30 Oct 2020 02:01:40

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:49:29
User entered 'No (N)'	System	31 Oct 2020 04:49:29

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:42
User entered 'None (1)'	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:42
User entered 'No (N)'	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:42
User entered 'No (N)'	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:22:42
User entered 'None (1)'	System	01 Nov 2020 01:22:42

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:34
User entered 'None (1)'	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:34
User entered 'No (N)'	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:34
User entered 'No (N)'	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:34
User entered 'None (1)'	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:09:34
User entered '01 Nov 2020 19:09'	System	02 Nov 2020 00:09:34

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:58
User entered 'None (1)'	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:58
User entered 'None (1)'	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:25:58
User entered '02 Nov 2020 22:25'	System	03 Nov 2020 03:25:58

US3352424

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'None (0)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered 'No (N)'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Oct 2020 16:18:27
User entered '27 Oct 2020 12:18'	System	27 Oct 2020 16:18:27

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'No interference with activity (1)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'No interference with activity (1)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'None (0)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'None (0)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'None (0)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'None (0)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered 'No (N)'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Oct 2020 01:59:08
User entered '27 Oct 2020 21:59'	System	28 Oct 2020 01:59:08

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered 'None (0)'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Oct 2020 00:04:19
User entered '28 Oct 2020 20:04'	System	29 Oct 2020 00:04:19

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:06:26
User entered 'None (0)'	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:06:26
User entered 'None (0)'	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:06:26
User entered 'None (0)'	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:06:26
User entered 'No (N)'	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Oct 2020 02:06:26
User entered '29 Oct 2020 22:06'	System	30 Oct 2020 02:06:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:50:53
User entered 'None (0)'	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:50:53
User entered 'None (0)'	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:50:53
User entered 'None (0)'	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	31 Oct 2020 04:50:53
User entered 'None (0)'	System	31 Oct 2020 04:50:53

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:23:26
User entered 'None (0)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:23:26
User entered 'None (0)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:23:26
User entered 'None (0)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:23:26
User entered 'None (0)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	01 Nov 2020 01:23:26
User entered 'No (N)'	System	01 Nov 2020 01:23:26

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'None (0)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'None (0)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'None (0)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'None (0)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'None (0)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered 'No (N)'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 00:10:13
User entered '01 Nov 2020 19:10'	System	02 Nov 2020 00:10:13

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

FATIGUE

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'None (0)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'None (0)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'None (0)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'None (0)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

CHILLS

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'None (0)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered 'No (N)'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 03:26:40
User entered '02 Nov 2020 22:26'	System	03 Nov 2020 03:26:40

US3352424

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
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'	System	04 Nov 2020 05:08:13
User entered 'None (0)'	System	04 Nov 2020 05:08:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:01:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Nov 2020 05:08:13
User entered '04 Nov 2020 00:08'	System	04 Nov 2020 05:08:13

US3352424

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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'	System	04 Nov 2020 05:08:27
User entered 'No (N)'	System	04 Nov 2020 05:08:27

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Nov 2020 05:08:27
User entered '04 Nov 2020 00:08'	System	04 Nov 2020 05:08:27

US3352424

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Yulexis Amestoy (b) (4) (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4) (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	04 Nov 2020 17:44:03

US3352424

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	04 Nov 2020 17:44:08

US3352424

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 17:44:08

US3352424

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:44:55

US3352424

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 20:45:05

US3352424

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:19:15

US3352424

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 20:19:20

US3352424

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

Have you been exposed to someone with 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: 26 Nov 2020 11:01:40

[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-e2ebdebcd70'	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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[AEID](#)

Audit	User	Time (GMT)
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 'USA-US066-2020-mRNA-1273-P301000002'	System	22 Oct 2020 17:25:35
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 17:25:35

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User coded data point as SOC: Cardiac disorders, HLT: 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.	Coder Import (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

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

End time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:18:04
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change:	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:18:04
New Information	(b) (4)	
DataPoint Verified.	(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: 26 Nov 2020 11:01:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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) (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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) (b) (4)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[None](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PER CDM-Concomitant Medication is checked, 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)	17 Nov 2020 14:51:44
User opened query 'PER CDM-Concomitant Medication is checked, 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)	21 Oct 2020 19:49:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Outcome](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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). DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 13:47:20
	(b) (4)	
	(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
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

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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. 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	(b) (4)	21 Oct 2020 19:52:42
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)	21 Oct 2020 19:49:45

US3352424

Folder: Adverse Events

Form: Adverse Events (1)

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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)

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[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	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
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:54:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

End time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:34:23
User entered '1'	Rosaidaliz Carreira (b) (4)	21 Oct 2020 19:54:35
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[None](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Outcome](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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.

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: 26 Nov 2020 11:01:40

Serious Adverse Event 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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: 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: 26 Nov 2020 11:01:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

End time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

None

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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		
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)	17 Nov 2020 17:56:18

US3352424

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:28:51
User entered 'USA-US066-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	18 Nov 2020 17:28:46

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: 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: 26 Nov 2020 11:01:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

None

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Outcome](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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)	(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: 26 Nov 2020 11:01:40

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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 19:14:08

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:29:24
User entered 'USA-US066-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	18 Nov 2020 17:29:21

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[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)	17 Nov 2020 19:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 19:17:49
Data point term sent to Coder	System	17 Nov 2020 19:17:32
User entered 'HYPERTENSION'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

None

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Narrative](#)

Audit	User	Time (GMT)
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)	(b) (4) 17 Nov 2020 19:17:20

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 (5)

Generated On: 26 Nov 2020 11:01:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 19:17:20

US3352424

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:01:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 19:17:20

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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	System	21 Oct 2020 19:56:14
User entered 'TERAZOSIN'	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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered '1'	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: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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 19:56:08
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERLIPIDEMIA'	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: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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 19:57:35
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

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 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'GASTRO REFLUX PREVENTION'	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: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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 20:03:18
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Name of Medication

Audit	User	Time (GMT)
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.	(b) (4) Rosaidaliz Carreira (b) (4)	17 Nov 2020 19:22:34
User entered 'VYTORIN' reason for change: Data Entry Error	(b) (4) Rosaidaliz Carreira (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)	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: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'HYPERLIPIDEMIA'	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: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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 20:05:53
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'cardiovascular prophylaxis'	Matthew Muniz (b) (4) (b) (4)	29 Oct 2020 20:20:05

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Name of Medication](#)

Audit	User	Time (GMT)
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 Coding entries removed.	System Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 14:52:06 17 Nov 2020 14:51:13
DataPoint Verified.	(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) (b) (4)	29 Oct 2020 20:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:24:45
Data point term sent to Coder User entered 'metoprolol er'	System Matthew Muniz (b) (4) (b) (4)	29 Oct 2020 20:24:00 29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 14:51:13
	(b) (4)	
User entered 'HYPERTENSION/TACHYCARDIA'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 14:51:13
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'hypertension'	Matthew Muniz (b) (4)	29 Oct 2020 20:23:01
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Dose per administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Dose unit](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:37:41
User entered 'once daily (QD)'	Matthew Muniz (b) (4) (b) (4)	29 Oct 2020 20:23:01

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Route of administration](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Ongoing?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3352424

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[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: 26 Nov 2020 11:01:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 20:23:01

US3352424

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:40

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Death

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 17:29:59