

US3322048 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:59:01

All time stamps listed in this document are displayed in GMT

US3322048

Form: Participant Creation

Generated On: 26 Nov 2020 10:59:01

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input 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 10:59:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

Condition	ROSACEA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

Condition	BILATERAL TUBAL OCCLUSION, STERILIZATION PROCEDURE
Start date (dd MMM yyyy)	21 FEB 2002
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)	21 FEB 2002
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2002
Start Year (derived)	2002
Stop Month and Year (derived)	FEB 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

Condition	TETRACYCLINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	21 FEB 2002
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)	21 FEB 2002
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2002
Start Year (derived)	2002
Stop Month and Year (derived)	FEB 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

Condition	SPONTANEOUS ABORTION
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

Condition	DILATION AND CURETTAGE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:35 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 09:35
Height (<i>xxx.x</i>)	62.5 in
Weight (<i>xxx.x</i>)	162 lb
BMI (<i>xxx.x</i>)	29.21897 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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 10:59:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 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: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	21 FEB 2002
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

SUBJECT IS A SCHOOL (b) (6)	
WILL BE GOING BACK TO	
WORK MONDAY, 24AUG2020,	
2-3X WEEK AND FULLTIME	
LATER IN THE SCHOOL	
YEAR.IN CONTACT WITH >5	
PEOPLE IN TYPICAL WORK	
DAY. HUSBAND WORKS AS	
PROPERTY MANAGER	
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
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	True
Specify	SUBJECT LIVES IN HOUSE WITH HUSBAND AND 3 KIDS.ONE WILL BE STARTING IN-PERSON CLASSES THIS YEAR. DINES AT RESTAURANTS 2X MONTH GROCERY SHOPPING ~2X WEEK. WALKS DOG 1-2X DAYS IN CONTACT W/ ~20 PEOPLE

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106172

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 10:59:01

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 10:59:01

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)	20 AUG 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 09:35
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 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 10:59:01

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)	20 AUG 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

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 10:59:01

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 11:36 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 11:36

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:42 (24 HR)
Collection date and time (derived)	20 AUG 2020 10:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:01

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:39	20 AUG 2020 10:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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 10:59:01

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

98.2 °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

20 AUG 2020 12:11

PC Open Date & Time

20 AUG 2020 11:56

PC Close Date & Time

20 AUG 2020 14:26

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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 98.3 °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	20 AUG 2020 20:01
PC Open Date & Time	20 AUG 2020 15:21
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

99.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 19:08

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:51

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 AUG 2020 21:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

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

96.6 °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 AUG 2020 22:12

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 20:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 12:12

PC Open Date & Time

20 AUG 2020 11:56

PC Close Date & Time

20 AUG 2020 14:26

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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

20 AUG 2020 20:02

PC Open Date & Time

20 AUG 2020 15:21

PC Close Date & Time

21 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

21 AUG 2020 19:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

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

22 AUG 2020 19:52

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

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

23 AUG 2020 21:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

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

24 AUG 2020 22:12

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

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

25 AUG 2020 20:11

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

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

26 AUG 2020 20:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 12:12
PC Open Date & Time	20 AUG 2020 11:56
PC Close Date & Time	20 AUG 2020 14:26

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:03
PC Open Date & Time	20 AUG 2020 15:21
PC Close Date & Time	21 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:09
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:53
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:37
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 22:13
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:11
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

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 ☒

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3322048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

6 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3 UNSUCCESSFUL ATTEMPT TO
CONTACT SUBJECT

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 08:42
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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? _____

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

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3322048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	18 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:25 (24 HR)
Collection date and time (derived)	18 SEP 2020 09:25

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:01

Collection date (<i>dd MMM yyyy</i>)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:19	18 SEP 2020 09:19
Nasopharyngeal Swab 2	No		

US3322048

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:55 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 15:55
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3322048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:25 (24 HR)
Collection date and time (derived)	19 OCT 2020 16:25

US3322048

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 10:59:09

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 14:16:50

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 12:21:35

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 09:01:27

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 12:13:37

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 187

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 208

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 <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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	06 APR 2022 23:59
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US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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="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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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 ☐

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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"/>

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted?

Yes ☒

No ☐

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

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322048

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322048

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

Date of Contact

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☐

No ☐

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:59:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322048

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

AEID	
Adverse event	FINGER STRAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	309 of 1367

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:01

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

Yes ☒

No ☐

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

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INJECTION SITE PAIN
Dose per administration	325
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 checked="" 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"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

	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)		21 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		22 AUG 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input checked="" 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"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

Name of Medication	VITAMIN D3
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	VITAMIN D DEFICIENCY
Dose per administration	50000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" 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 checked="" 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"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FINGER STRAIN
Dose per administration	400
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"/>

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

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

US3322048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:01

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3322048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:01

Date of dosing discontinuation (dd MMM yyyy)

25 AUG 2020

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 _____

US3322048

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:01

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 ☐

Audit

US3322048 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322048

Form: Participant Creation

Generated On: 26 Nov 2020 10:59:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322048'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 14:24:26

US3322048

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:59:17

US3322048

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 14:24:26

US3322048

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 15:59:17

US3322048

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	20 Aug 2020 15:59:17

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 14:24:27

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Age](#)

Audit	User	Time (GMT)
User entered '51'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:01

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:41

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:00:23

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 14:24:26

US3322048

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:31

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 20:57:06
Query 'Per DM CLR: Please note that there is no Con Blessing Felix-Okoroji Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con Meds updated with treatment medication (Levothyroxine)' (Site from DM).	(b) (4)	28 Sep 2020 14:41:27
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:21:29
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 16:19:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 16:19:24
Data point term sent to Coder	System	20 Aug 2020 16:18:37
User entered 'Hypothyroidism'	Elisa Moralez (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2010'	System	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:17:57

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:19:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:19:24
Data point term sent to Coder	System	20 Aug 2020 16:18:38
User entered 'Rosacea'	Elisa Moralez (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:18:12

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Female sterilisation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 08:39:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 08:39:49
Data point term sent to Coder	System	31 Aug 2020 13:35:21
User closed query 'For coding purposes, for term BILATERAL TUBAL OCCLUSION, please clarify/provide more information. Is this a sterilization procedure, pelvic adhesions or something else. Please update the term with your response' (Site from System).	System	31 Aug 2020 13:34:40
Query 'For coding purposes, for term BILATERAL TUBAL OCCLUSION, please clarify/provide more information. Is this a sterilization procedure, pelvic adhesions or something else. Please update the term with your response' answered with 'Changed data per query resolution; BILATERAL TUBAL OCCLUSION, STERILIZATION PROCEDURE' (Site from System).	Frances Saubon (b) (4)	31 Aug 2020 13:34:40
Data point term sent to Coder	System	31 Aug 2020 13:33:17
User entered 'BILATERAL TUBAL OCCLUSION, STERILIZATION PROCEDURE' reason for change: Data Entry Error	Frances Saubon (b) (4)	31 Aug 2020 13:33:15
User opened query 'For coding purposes, for term BILATERAL TUBAL OCCLUSION, please clarify/provide more information. Is this a sterilization procedure, pelvic adhesions or something else. Please update the term with your response' (Site from System).	Coder Import (b) (4)	30 Aug 2020 14:32:30
Data point term sent to Coder	System	20 Aug 2020 16:18:39
User entered 'Bilateral Tubal Occlusion'	Elisa Moralez (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '21 Feb 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 16:18:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 16:18:56
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:56
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 16:18:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '21 Feb 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Feb 2002'	System	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Feb 2002'	System	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:18:29

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 10:53:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 10:53:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:03:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:03:44
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:20:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:20:18
Data point term sent to Coder	System	20 Aug 2020 16:19:42
User entered 'Tetracycline Allergy'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:18:47

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:20:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:20:18
Data point term sent to Coder	System	20 Aug 2020 16:19:44
User entered 'Cesarean Section'	Elisa Moralez (b) (4)	20 Aug 2020 16:19:41
	(b) (4)	

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '21 Feb 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '21 Feb 2002'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Feb 2002'	System	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Feb 2002'	System	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 16:19:41

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Spontaneous abortion - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:21:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:21:20
Data point term sent to Coder	System	20 Aug 2020 16:20:47
User entered 'Spontaneous Abortion'	Elisa Moralez (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '1998'	System	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '1998'	System	20 Aug 2020 16:20:00

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: Uterine dilation and curettage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:21:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:21:20
Data point term sent to Coder	System	20 Aug 2020 16:20:48
User entered 'Dilation and curettage'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '1998'	System	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '1998'	System	20 Aug 2020 16:20:18

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:21:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:21:21
Data point term sent to Coder	System	20 Aug 2020 16:20:48
User entered 'Vitamin D Deficiency'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'UN Jun 2019'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 16:20:33

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if time 09:35 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:57:06
Query 'Per CDM: Please confirm if time 09:35 is AM or PM. Thank you.' answered with '9:35 AM' (Site from DM).	Blessing Felix-Okoroji (b) (4)	24 Sep 2020 19:56:31
User opened query 'Per CDM: Please confirm if time 09:35 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:00:24
User entered '09:35'	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 09:35'	System	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Height (xxx.x)

Audit	User	Time (GMT)
User entered '62.5' in	(b) (4), (b) (6)	20 Aug 2020 16:02:48
DataPoint set to visible.	System	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '162' lb	(b) (4), (b) (6)	20 Aug 2020 16:02:48
DataPoint set to visible.	System	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '29.21897'	System	17 Sep 2020 00:15:47
User entered '29.2'	System	20 Aug 2020 16:02:48
DataPoint set to visible.	System	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	20 Aug 2020 16:02:48
DataPoint set to visible.	System	20 Aug 2020 16:00:37

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 16:02:48

US3322048

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:03:05

US3322048

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:03:05

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Feb 2002'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:01

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:03:46

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[Specify](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A SCHOOL (b) (6) WILL BE GOING BACK TO WORK MONDAY, 24AUG2020, 2-3x WEEK AND FULLTIME LATER IN THE SCHOOL YEAR.IN CONTACT WITH >5 PEOPLE IN TYPICAL WORK DAY. HUSBAND WORKS AS PROPERTY MANAGER' reason for change: New Information	Frances Saubon (b) (4)	21 Aug 2020 13:21:54
User entered 'SUBJECT IS A SCHOOL (b) (6) THAT WILL BE GOING BACK TO WORK MONDAY, 24AUG2020, 2-3 TIMES A WEEK AND FULL-TIME LATER IN THE SCHOOL YEAR.IS IN CONTACT WITH MORE THAN 5 PEOPLE IN A TYPICAL WORK DAY.' reason for change: New Information	Elisa Moralez (b) (4)	20 Aug 2020 16:17:05
User closed query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	20 Aug 2020 16:16:51
User entered 'Subject is a School (b) (6) that will be going back to work Monday, 24Aug2020, 2-3 times a week and full-time later in the school year.Subject drives her own car to work and is in contact with more than 5 people in a typical work day.' (non-conformant).	Elisa Moralez (b) (4)	20 Aug 2020 16:16:51
User opened query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	20 Aug 2020 16:04:55
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 16:04:55

US3322048

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:01

[Specify](#)

Audit	User	Time (GMT)
User entered 'SUBJECT LIVES IN HOUSE WITH HUSBAND AND 3 KIDS.ONE WILL BE STARTING IN-PERSON CLASSES THIS YEAR. DINES AT RESTAURANTS 2X MONTH GROCERY SHOPPING ~2X WEEK. WALKS DOG 1-2X DAYS IN CONTACT W/ ~20 PEOPLE' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Aug 2020 13:21:54
User closed query 'Location and Living Circumstances Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	20 Aug 2020 16:16:51
User entered 'Subject lives in a house with her husband and 3 kids. One of her kids will be starting in-person classes this year. Her husband works FT as a property manager. Subject dine-in at restaurants 2x month, grocery shopping approx 2x week' (non-conformant).	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 16:16:51
User opened query 'Location and Living Circumstances Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	20 Aug 2020 16:04:55
User entered empty.	(b) (4), (b) (6) (b) (4) (b) (4) (b) (4)	20 Aug 2020 16:04:55

US3322048

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:27:47

US3322048

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:27:47

US3322048

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:27:47

US3322048

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	20 Aug 2020 17:27:47

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 15:40:24

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:49:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:49:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 15:40:24
User entered '106172' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 15:40:24

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

[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]	20 Aug 2020 15:40:24

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

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)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:28:03

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:28:03

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:28:03

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:28:03

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:28:03

US3322048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4)	24 Sep 2020 15:22:18
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:36:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:42:41

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '09:35'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 09:35'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Pulse (xxx)

Audit	User	Time (GMT)
User entered '74'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '16'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:49:50
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per source' (Site from System).	Elisa Moralez (b) (4)	20 Aug 2020 17:30:26
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 17:30:12
User entered '12:08'	Elisa Moralez (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:08'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Pulse (xxx)

Audit	User	Time (GMT)
User entered '72'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '18'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:30:12

US3322048

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:32

US3322048

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:32

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '11:36'	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:36'	System	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 16:38:15

US3322048

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:44

US3322048

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:44

US3322048

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:42'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:44

US3322048

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:42'	System	20 Aug 2020 17:30:44

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:39'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:39'	System	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:57

US3322048

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Aug 2020 17:31:00

US3322048

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:31:00

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:20', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0211284f-62ce-4dc0-8b93-f970dc2b4d02'	System	20 Aug 2020 17:11:52
User entered 'Yes (Y)'	System	20 Aug 2020 17:11:52

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:26', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0211284f-62ce-4dc0-8b93-f970dc2b4d02'	System	20 Aug 2020 17:11:52
User entered '98.2'	System	20 Aug 2020 17:11:52

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:32', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0211284f-62ce-4dc0-8b93-f970dc2b4d02'	System	20 Aug 2020 17:11:52
User entered 'No (N)'	System	20 Aug 2020 17:11:52

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:44', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0211284f-62ce-4dc0-8b93-f970dc2b4d02'	System	20 Aug 2020 17:11:52
User entered '20 Aug 2020 12:11'	System	20 Aug 2020 17:11:52

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:56'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:26'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:00:50', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '115ae103-7085-4209-bc5a-56254c2012c6'	System	21 Aug 2020 01:01:20
User entered 'Yes (Y)'	System	21 Aug 2020 01:01:20

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:00:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '115ae103-7085-4209-bc5a-56254c2012c6'	System	21 Aug 2020 01:01:20
User entered '98.3'	System	21 Aug 2020 01:01:20

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:01:04', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '115ae103-7085-4209-bc5a-56254c2012c6'	System	21 Aug 2020 01:01:20
User entered 'No (N)'	System	21 Aug 2020 01:01:20

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:01:16', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '115ae103-7085-4209-bc5a-56254c2012c6'	System	21 Aug 2020 01:01:20
User entered '20 Aug 2020 20:01'	System	21 Aug 2020 01:01:20

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:21'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 2'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:53', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered 'Yes (Y)'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:02', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered '99.3'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:07', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered 'Yes (Y)'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 18:16:48
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'followup call revealed patient had soreness at injection site, took medication twice in one day to ease pain, has not taken since' (Site from System).	Elisa Moralez (b) (4)	22 Aug 2020 16:07:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Aug 2020 00:08:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:18', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered '1'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:18', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered '0'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:27', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f9bec38-af6a-46df-b909-2884bbc325c7'	System	22 Aug 2020 00:08:29
User entered '21 Aug 2020 19:08'	System	22 Aug 2020 00:08:29

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 3'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:51:17', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e91a5f17-8877-4520-ab3b-5a1de98e0263'	System	23 Aug 2020 00:51:54
User entered 'Yes (Y)'	System	23 Aug 2020 00:51:54

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:51:31', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e91a5f17-8877-4520-ab3b-5a1de98e0263'	System	23 Aug 2020 00:51:54
User entered '97.3'	System	23 Aug 2020 00:51:54

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:51:40', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e91a5f17-8877-4520-ab3b-5a1de98e0263'	System	23 Aug 2020 00:51:54
User entered 'No (N)'	System	23 Aug 2020 00:51:54

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:51:50', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e91a5f17-8877-4520-ab3b-5a1de98e0263'	System	23 Aug 2020 00:51:54
User entered '22 Aug 2020 19:51'	System	23 Aug 2020 00:51:54

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 4'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:01', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ac9fc1bb-d43c-4a8b-a292-7c90f8faaeef'	System	24 Aug 2020 02:36:17
User entered 'Yes (Y)'	System	24 Aug 2020 02:36:17

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:08', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ac9fc1bb-d43c-4a8b-a292-7c90f8faaeef'	System	24 Aug 2020 02:36:17
User entered '97.6'	System	24 Aug 2020 02:36:17

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:11', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ac9fc1bb-d43c-4a8b-a292-7c90f8faaeef'	System	24 Aug 2020 02:36:17
User entered 'No (N)'	System	24 Aug 2020 02:36:17

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:15', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ac9fc1bb-d43c-4a8b-a292-7c90f8faaeef'	System	24 Aug 2020 02:36:17
User entered '23 Aug 2020 21:36'	System	24 Aug 2020 02:36:17

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 5'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:11:49', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '56ca8717-a214-4677-92c4-121f61147e12'	System	25 Aug 2020 03:12:12
User entered 'Yes (Y)'	System	25 Aug 2020 03:12:12

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:11:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '56ca8717-a214-4677-92c4-121f61147e12'	System	25 Aug 2020 03:12:12
User entered '96.6'	System	25 Aug 2020 03:12:12

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:02', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '56ca8717-a214-4677-92c4-121f61147e12'	System	25 Aug 2020 03:12:12
User entered 'No (N)'	System	25 Aug 2020 03:12:12

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:10', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '56ca8717-a214-4677-92c4-121f61147e12'	System	25 Aug 2020 03:12:12
User entered '24 Aug 2020 22:12'	System	25 Aug 2020 03:12:12

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 6'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:29', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fae1973c-42c2-4c8d-bb6a-29439a3fb9bc'	System	26 Aug 2020 01:10:51
User entered 'Yes (Y)'	System	26 Aug 2020 01:10:51

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:35', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fae1973c-42c2-4c8d-bb6a-29439a3fb9bc' User entered '97.8'	System	26 Aug 2020 01:10:51

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:40', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fae1973c-42c2-4c8d-bb6a-29439a3fb9bc'	System	26 Aug 2020 01:10:51
User entered 'No (N)'	System	26 Aug 2020 01:10:51

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:44', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fae1973c-42c2-4c8d-bb6a-29439a3fb9bc'	System	26 Aug 2020 01:10:51
User entered '25 Aug 2020 20:10'	System	26 Aug 2020 01:10:51

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 7'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:01:46', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3468ba26-9924-4a33-b132-242e95ad7a21'	System	27 Aug 2020 01:02:10
User entered 'Yes (Y)'	System	27 Aug 2020 01:02:10

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:01:54', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3468ba26-9924-4a33-b132-242e95ad7a21'	System	27 Aug 2020 01:02:10
User entered '97.7'	System	27 Aug 2020 01:02:10

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:01:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3468ba26-9924-4a33-b132-242e95ad7a21'	System	27 Aug 2020 01:02:10
User entered 'No (N)'	System	27 Aug 2020 01:02:10

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:03', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3468ba26-9924-4a33-b132-242e95ad7a21'	System	27 Aug 2020 01:02:10
User entered '26 Aug 2020 20:02'	System	27 Aug 2020 01:02:10

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:55', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f247459-8028-47a6-b207-1c5da70da2dd'	System	20 Aug 2020 17:12:20
User entered 'None (1)'	System	20 Aug 2020 17:12:20

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:11:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f247459-8028-47a6-b207-1c5da70da2dd'	System	20 Aug 2020 17:12:20
User entered 'No (N)'	System	20 Aug 2020 17:12:20

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:02', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f247459-8028-47a6-b207-1c5da70da2dd'	System	20 Aug 2020 17:12:20
User entered 'No (N)'	System	20 Aug 2020 17:12:20

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:08', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f247459-8028-47a6-b207-1c5da70da2dd'	System	20 Aug 2020 17:12:20
User entered 'None (1)'	System	20 Aug 2020 17:12:20

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:13', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '0f247459-8028-47a6-b207-1c5da70da2dd'	System	20 Aug 2020 17:12:20
User entered '20 Aug 2020 12:12'	System	20 Aug 2020 17:12:20

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:56'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:26'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:01:37', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '5d980fef-bdf1-4961-a23e-a7e1c926bdf3'	System	21 Aug 2020 01:02:13
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 01:02:13

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:01:40', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '5d980fef-bdf1-4961-a23e-a7e1c926bdf3'	System	21 Aug 2020 01:02:13
User entered 'No (N)'	System	21 Aug 2020 01:02:13

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:01:54', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '5d980fef-bdf1-4961-a23e-a7e1c926bdf3'	System	21 Aug 2020 01:02:13
User entered 'No (N)'	System	21 Aug 2020 01:02:13

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:01', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '5d980fef-bdf1-4961-a23e-a7e1c926bdf3'	System	21 Aug 2020 01:02:13
User entered 'None (1)'	System	21 Aug 2020 01:02:13

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:10', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '5d980fef-bdf1-4961-a23e-a7e1c926bdf3'	System	21 Aug 2020 01:02:13
User entered '20 Aug 2020 20:02'	System	21 Aug 2020 01:02:13

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:21'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 2'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:17', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '68050f11-3751-4383-9a9f-4600466dbf76'	System	22 Aug 2020 00:07:49
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 00:07:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:20', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '68050f11-3751-4383-9a9f-4600466dbf76'	System	22 Aug 2020 00:07:49
User entered 'No (N)'	System	22 Aug 2020 00:07:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:27', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '68050f11-3751-4383-9a9f-4600466dbf76'	System	22 Aug 2020 00:07:49
User entered 'No (N)'	System	22 Aug 2020 00:07:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:34', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '68050f11-3751-4383-9a9f-4600466dbf76'	System	22 Aug 2020 00:07:49
User entered 'None (1)'	System	22 Aug 2020 00:07:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:07:45', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '68050f11-3751-4383-9a9f-4600466dbf76'	System	22 Aug 2020 00:07:49
User entered '21 Aug 2020 19:07'	System	22 Aug 2020 00:07:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 3'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:51:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '027ba43e-cbb8-4f1a-aac5-3248dc8f67fa'	System	23 Aug 2020 00:52:49
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 00:52:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:04', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '027ba43e-cbb8-4f1a-aac5-3248dc8f67fa'	System	23 Aug 2020 00:52:49
User entered 'No (N)'	System	23 Aug 2020 00:52:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:27', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '027ba43e-cbb8-4f1a-aac5-3248dc8f67fa'	System	23 Aug 2020 00:52:49
User entered 'No (N)'	System	23 Aug 2020 00:52:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:37', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '027ba43e-cbb8-4f1a-aac5-3248dc8f67fa' User entered 'None (1)'	System	23 Aug 2020 00:52:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:45', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '027ba43e-cbb8-4f1a-aac5-3248dc8f67fa'	System	23 Aug 2020 00:52:49
User entered '22 Aug 2020 19:52'	System	23 Aug 2020 00:52:49

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 4'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:23', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1047873-5d59-4334-881a-613930ea635e'	System	24 Aug 2020 02:37:00
User entered 'None (1)'	System	24 Aug 2020 02:37:00

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:26', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1047873-5d59-4334-881a-613930ea635e'	System	24 Aug 2020 02:37:00
User entered 'No (N)'	System	24 Aug 2020 02:37:00

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:29', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1047873-5d59-4334-881a-613930ea635e'	System	24 Aug 2020 02:37:00
User entered 'No (N)'	System	24 Aug 2020 02:37:00

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:36', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1047873-5d59-4334-881a-613930ea635e'	System	24 Aug 2020 02:37:00
User entered 'None (1)'	System	24 Aug 2020 02:37:00

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:36:57', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1047873-5d59-4334-881a-613930ea635e'	System	24 Aug 2020 02:37:00
User entered '23 Aug 2020 21:36'	System	24 Aug 2020 02:37:00

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 5'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:14', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ae7ef9ba-b79f-4610-aad9-a47719df954f'	System	25 Aug 2020 03:12:50
User entered 'None (1)'	System	25 Aug 2020 03:12:50

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:17', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ae7ef9ba-b79f-4610-aad9-a47719df954f'	System	25 Aug 2020 03:12:50
User entered 'No (N)'	System	25 Aug 2020 03:12:50

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:20', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ae7ef9ba-b79f-4610-aad9-a47719df954f'	System	25 Aug 2020 03:12:50
User entered 'No (N)'	System	25 Aug 2020 03:12:50

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ae7ef9ba-b79f-4610-aad9-a47719df954f'	System	25 Aug 2020 03:12:50
User entered 'None (1)'	System	25 Aug 2020 03:12:50

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:47', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ae7ef9ba-b79f-4610-aad9-a47719df954f'	System	25 Aug 2020 03:12:50
User entered '24 Aug 2020 22:12'	System	25 Aug 2020 03:12:50

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 6'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:48', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd7927e3e-2831-4634-8262-c3871c962ae9'	System	26 Aug 2020 01:11:16
User entered 'None (1)'	System	26 Aug 2020 01:11:16

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:52', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd7927e3e-2831-4634-8262-c3871c962ae9'	System	26 Aug 2020 01:11:16
User entered 'No (N)'	System	26 Aug 2020 01:11:16

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:10:58', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd7927e3e-2831-4634-8262-c3871c962ae9'	System	26 Aug 2020 01:11:16
User entered 'No (N)'	System	26 Aug 2020 01:11:16

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:02', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd7927e3e-2831-4634-8262-c3871c962ae9'	System	26 Aug 2020 01:11:16
User entered 'None (1)'	System	26 Aug 2020 01:11:16

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:11', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd7927e3e-2831-4634-8262-c3871c962ae9'	System	26 Aug 2020 01:11:16
User entered '25 Aug 2020 20:11'	System	26 Aug 2020 01:11:16

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 7'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:08', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e467a732-5858-481d-8891-0f5ef6db582c'	System	27 Aug 2020 01:02:38
User entered 'None (1)'	System	27 Aug 2020 01:02:38

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:13', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e467a732-5858-481d-8891-0f5ef6db582c'	System	27 Aug 2020 01:02:38
User entered 'No (N)'	System	27 Aug 2020 01:02:38

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:17', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e467a732-5858-481d-8891-0f5ef6db582c'	System	27 Aug 2020 01:02:38
User entered 'No (N)'	System	27 Aug 2020 01:02:38

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:22', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e467a732-5858-481d-8891-0f5ef6db582c'	System	27 Aug 2020 01:02:38
User entered 'None (1)'	System	27 Aug 2020 01:02:38

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:30', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'e467a732-5858-481d-8891-0f5ef6db582c'	System	27 Aug 2020 01:02:38
User entered '26 Aug 2020 20:02'	System	27 Aug 2020 01:02:38

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:18', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:21', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:26', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:28', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:30', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'None (0)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:36', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered 'No (N)'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T12:12:49', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '130426b7-84a9-4f03-8df7-c07e3ce6c759'	System	20 Aug 2020 17:12:54
User entered '20 Aug 2020 12:12'	System	20 Aug 2020 17:12:54

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:56'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:26'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'None (0)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:45', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:51', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:55', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:02:58', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'None (0)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:03:07', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'No interference with activity (1)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:03:16', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered 'No (N)'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-20T20:03:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '92859011-0abf-4efa-ad54-be03ee2e9ed4'	System	21 Aug 2020 01:03:25
User entered '20 Aug 2020 20:03'	System	21 Aug 2020 01:03:25

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:21'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 2'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:34', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:39', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:46', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'None (0)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:49', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'None (0)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:52', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'None (0)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:08:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'None (0)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:09:07', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered 'No (N)'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-21T19:09:17', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '2da40b7f-53a3-4c71-a547-bd2db97d1ef7'	System	22 Aug 2020 00:09:21
User entered '21 Aug 2020 19:09'	System	22 Aug 2020 00:09:21

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 3'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:50', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:52:57', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:01', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:05', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:07', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:09', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'None (0)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:16', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered 'No (N)'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-22T19:53:23', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'd1253138-4848-4b4e-9c7e-77b2aa7add67'	System	23 Aug 2020 00:53:27
User entered '22 Aug 2020 19:53'	System	23 Aug 2020 00:53:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 4'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:03', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:06', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:08', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:13', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:15', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:18', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'None (0)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered 'No (N)'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-23T21:37:40', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'f88d806a-ff72-44df-aea8-bcdc11e9d18f'	System	24 Aug 2020 02:37:41
User entered '23 Aug 2020 21:37'	System	24 Aug 2020 02:37:41

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 5'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:52', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:54', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:57', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:12:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:13:01', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:13:03', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'None (0)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:13:06', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered 'No (N)'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-24T22:13:16', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'fc4991d0-1ce9-4476-a615-d3518685a403'	System	25 Aug 2020 03:13:20
User entered '24 Aug 2020 22:13'	System	25 Aug 2020 03:13:20

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 6'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:16', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:20', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:22', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:25', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:27', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:29', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'None (0)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:34', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered 'No (N)'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-25T20:11:46', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '02fcee6d-548d-496c-a763-47c4716860a2'	System	26 Aug 2020 01:11:48
User entered '25 Aug 2020 20:11'	System	26 Aug 2020 01:11:48

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 7'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:35', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:38', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:41', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:45', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:48', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:02:50', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'None (0)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:03:01', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered 'No (N)'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-08-26T20:03:24', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '8b5fc405-8459-41f9-8525-1816d37ff123'	System	27 Aug 2020 01:03:27
User entered '26 Aug 2020 20:03'	System	27 Aug 2020 01:03:27

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:38:15

US3322048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:58:28

US3322048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:58:28

US3322048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:58:28

US3322048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:58:28

US3322048

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:58:17

US3322048

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 13:58:17

US3322048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:04:15

US3322048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '6 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:04:15

US3322048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	09 Sep 2020 13:04:27
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	09 Sep 2020 13:04:15

US3322048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '3 unsuccessful attempt to contact subject'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:04:15

US3322048

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:04:19

US3322048

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 13:04:19

US3322048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:54:41

US3322048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:54:41

US3322048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:54:41

US3322048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:54:41

US3322048

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:54:44

US3322048

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 20:54:44

US3322048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:14:43

US3322048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:14:43

US3322048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:14:43

US3322048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	18 Sep 2020 20:14:43

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '08:42'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 08:42'	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '16'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:03

US3322048

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:18

US3322048

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:18

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:39:12
Query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' answered with 'will do once Source is updated' (Site from DM).	Elisa Moralez (b) (4)	28 Sep 2020 14:56:47
User opened query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4)	
User entered 'Confirmed COVID-19 (COVID)'	(b) (4), (b) (6)	22 Sep 2020 15:21:47
	Elisa Moralez (b) (4)	18 Sep 2020 20:16:28
	(b) (4)	

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:28

US3322048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:41

US3322048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:41

US3322048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:25'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:41

US3322048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 09:25'	System	18 Sep 2020 20:16:41

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:19'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 09:19'	System	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:16:53

US3322048

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 20:17:13

US3322048

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:17:13

US3322048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:55:29

US3322048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:55:29

US3322048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:55:29

US3322048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:55:29

US3322048

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:55:33

US3322048

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 13:55:33

US3322048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:08:37

US3322048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:08:37

US3322048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:08:37

US3322048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:08:37

US3322048

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:08:46

US3322048

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 15:08:46

US3322048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Oct 2020 15:46:42

US3322048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	12 Oct 2020 15:46:42

US3322048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	12 Oct 2020 15:46:42

US3322048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Oct 2020 15:46:42

US3322048

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Oct 2020 15:46:46

US3322048

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 15:46:46

US3322048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:37:21

US3322048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:37:21

US3322048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:37:21

US3322048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Oct 2020 21:37:21

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '15:55'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 15:55'	System	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Pulse (xxx)

Audit	User	Time (GMT)
User entered '83'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '15'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '94'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 21:38:24

US3322048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:39:14

US3322048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:39:14

US3322048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:39:30

US3322048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:39:30

US3322048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:25'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:39:30

US3322048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 16:25'	System	19 Oct 2020 21:39:30

US3322048

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 21:40:27

US3322048

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:40:27

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 64'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-21T10:57:59', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ad325b4c-9761-4e1d-8edc-ded16772fc7e' User entered 'No (N)'	System	21 Oct 2020 15:59:13
	System	21 Oct 2020 15:59:13

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Have you been exposed to someone with 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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-21T10:58:10', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ad325b4c-9761-4e1d-8edc-ded16772fc7e' User entered 'No (N)'	System	21 Oct 2020 15:59:13
	System	21 Oct 2020 15:59:13

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-21T10:59:09', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: 'ad325b4c-9761-4e1d-8edc-ded16772fc7e' User entered '21 Oct 2020 10:59:09'	System	21 Oct 2020 15:59:13
	System	21 Oct 2020 15:59:13

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 71'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-27T14:14:14', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3475b3cd-73e2-4216-9f3e-549a760d2f8d' User entered 'No (N)'	System	27 Oct 2020 19:16:53
	System	27 Oct 2020 19:16:53

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Have you been exposed to someone with 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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-27T14:14:23', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3475b3cd-73e2-4216-9f3e-549a760d2f8d' User entered 'No (N)'	System	27 Oct 2020 19:16:53
	System	27 Oct 2020 19:16:53

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-10-27T14:16:50', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '3475b3cd-73e2-4216-9f3e-549a760d2f8d' User entered '27 Oct 2020 14:16:50'	System	27 Oct 2020 19:16:53
	System	27 Oct 2020 19:16:53

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 78'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-03T12:21:05', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '684455f9-2479-4ebb-962f-330c836b34b4' User entered 'No (N)'	System	03 Nov 2020 18:21:39
	System	03 Nov 2020 18:21:39

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Have you been exposed to someone with 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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-03T12:21:15', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '684455f9-2479-4ebb-962f-330c836b34b4' User entered 'No (N)'	System	03 Nov 2020 18:21:39

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-03T12:21:35', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '684455f9-2479-4ebb-962f-330c836b34b4' User entered '03 Nov 2020 12:21:35'	System	03 Nov 2020 18:21:39
	System	03 Nov 2020 18:21:39

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered 'Day 92'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-18T09:00:40', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '7619fedd-5eca-4e28-832a-76980ed89c0e' User entered 'No (N)'	System	18 Nov 2020 15:01:31
	System	18 Nov 2020 15:01:31

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Have you been exposed to someone with 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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-18T09:00:51', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '7619fedd-5eca-4e28-832a-76980ed89c0e'	System	18 Nov 2020 15:01:31
User entered 'No (N)'	System	18 Nov 2020 15:01:31

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-18T09:01:27', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '7619fedd-5eca-4e28-832a-76980ed89c0e' User entered '18 Nov 2020 09:01:27'	System	18 Nov 2020 15:01:31
	System	18 Nov 2020 15:01:31

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 16:38:15

US3322048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:38:15
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 16:38:15

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-24T12:13:21', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '698e3150-aeb2-49c4-bddb-b3c9076b49d9'	System	24 Nov 2020 18:13:40
User entered 'No (N)'	System	24 Nov 2020 18:13:40

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

Have you been exposed to someone with 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 (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-24T12:13:29', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '698e3150-aeb2-49c4-bddb-b3c9076b49d9'	System	24 Nov 2020 18:13:40
User entered 'No (N)'	System	24 Nov 2020 18:13:40

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1605BA95-0D39-4045-AB87-6084E939FD4A)', Time: '2020-11-24T12:13:37', User OID: 'PatientReportedOutcome (US3322048)', ODM File OID: '698e3150-aeb2-49c4-bddb-b3c9076b49d9' User entered '24 Nov 2020 12:13:37'	System	24 Nov 2020 18:13:40
	System	24 Nov 2020 18:13:40

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:39:08

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:39:08

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

US3322048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

US3322048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:38:17

US3322048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:38:17

US3322048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:38:17

US3322048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:38:17

US3322048

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:38:21

US3322048

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 15:38:21

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

[Date of Contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 22:12:57
User entered '18 Sep 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 14:54:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4)	22 Sep 2020 07:20:24
Query 'Data is required. Please complete.' answered with 'Data was entered erroneously. ' (Site from System).	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 21:10:51
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 21:10:47
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 21:10:47
User entered '25 Aug 2020'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 22:51:13

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

[Time of Contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 22:12:57
User entered '08:32' reason for change: New Information	Elisa Moralez (b) (4)	28 Sep 2020 14:54:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:20:25
Query 'Data is required. Please complete.' answered with 'Data was entered erroneously. ' (Site from System).	Frances Saubon (b) (4)	21 Sep 2020 21:10:55
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 21:10:47
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 21:10:47
User entered '00:00'	Frances Saubon (b) (4)	18 Sep 2020 22:51:13

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 22:12:57
User entered '18 Sep 2020 08:32'	System	28 Sep 2020 14:54:59
User entered empty.	System	21 Sep 2020 21:10:47
User entered '25 Aug 2020 00:00'	System	18 Sep 2020 22:51:13

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

[Type of Contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 22:12:57
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: New Information	Elisa Moralez (b) (4)	28 Sep 2020 14:54:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:20:37
Query 'Data is required. Please complete.' answered with 'Data was entered erroneously. ' (Site from System).	Frances Saubon (b) (4)	21 Sep 2020 21:10:58
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 21:10:47
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 21:10:47
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Frances Saubon (b) (4)	18 Sep 2020 22:51:13

US3322048

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 22:12:57
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 14:54:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4)	22 Sep 2020 07:20:38
Query 'Data is required. Please complete.' answered with 'Data was entered erroneously. ' (Site from System).	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 21:11:01
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 21:10:47
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 21:10:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 22:51:13

US3322048

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	29 Oct 2020 18:42:20
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	28 Sep 2020 14:56:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	28 Sep 2020 14:55:32

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Finger sprain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 20:34:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 20:34:23
Data point term sent to Coder	System	29 Oct 2020 18:43:45
User entered 'Finger Strain'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Elisa Moralez (b) (4)	18 Nov 2020 16:21:14
User entered 'None (NONE)'	Elisa Moralez (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[None](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 18:43:04

US3322048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 18:43:04

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:00:34

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:48:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:48:17
Data point term sent to Coder	System	13 Oct 2020 16:48:03
Coding entries removed.	Blessing Felix-Okoroji	13 Oct 2020 16:47:48
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:08:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:08:16
Data point term sent to Coder	System	22 Aug 2020 16:07:01
User entered 'Tylenol'	Elisa Moralez (b) (4)	22 Aug 2020 16:06:58
	(b) (4)	

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:03:16
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'DATA HAS BEEN UPDATED. MEDICATION WAS TAKEN TO RELIEVE INJECTION SITE PAIN' (Site from DM).	Blessing Felix-Okoroji (b) (4)	13 Oct 2020 16:48:09
User entered 'INJECTION SITE PAIN' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	13 Oct 2020 16:47:48
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:38:29
User entered 'pain reduction'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '325' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:00
User entered '500'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Aug 2020' reason for change: New Information	Elisa Moralez (b) (4)	24 Sep 2020 15:22:49
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:06:58

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 15:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 15:25:52
Data point term sent to Coder	System	24 Sep 2020 15:24:14
User entered 'Levothyroxine'	Elisa Moralez (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroidism'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 15:23:33

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 15:26:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 15:26:21
Data point term sent to Coder	System	24 Sep 2020 15:25:15
User entered 'Vitamin D3'	Elisa Moralez (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Vitamin D Deficiency'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50000'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered 'un Jun 2019'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	24 Sep 2020 15:24:18

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:38:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:38:53
Data point term sent to Coder	System	28 Sep 2020 13:56:22
User entered 'Ibuprofen'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:52:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'now entered' (Site from DM).	Elisa Moralez (b) (4)	29 Oct 2020 18:43:22
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:53:42
User entered 'finger strain'	Elisa Moralez (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency = ONCE; however, this medication is still ongoing. Please verify and update the Frequency or start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:19:03
Query 'Per DM CLR: Please review the Frequency = ONCE; however, this medication is still ongoing. Please verify and update the Frequency or start/stop dates as appropriate.' answered with 'frequency updated to once daily' (Site from DM).	Blessing Felix-Okoroji (b) (4)	28 Oct 2020 17:09:27
User entered 'once daily (QD)' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	28 Oct 2020 17:09:00
User opened query 'Per DM CLR: Please review the Frequency = ONCE; however, this medication is still ongoing. Please verify and update the Frequency or start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:53:14
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 17:09:00
User entered empty.	System	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 17:09:00
User entered empty.	System	28 Sep 2020 13:56:20

US3322048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 17:09:00
User entered empty.	System	28 Sep 2020 13:56:20

US3322048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:01

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Frances Saubon (b) (4) (b) (4)	12 Oct 2020 16:45:02

US3322048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:44:26
Query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' answered with 'Patient was discontinued from IP due to SARS-COV-2 at baseline. However, patient is still participating in the study for appropriate follow-ups, therefore end of study page is not completed.' (Site from DM).	Frances Saubon (b) (4)	02 Nov 2020 16:45:12
User opened query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 04:11:04
User closed query 'Per CDM Requery-Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', however, no corresponding data is recorded on 'Covid -19 Assessment' form, 'Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:29:56
Query 'Per CDM Requery-Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', however, no corresponding data is recorded on 'Covid -19 Assessment' form, 'Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'as stated in earlier query answer, confirmed covid at baseline visit' (Site from DM).	Elisa Moralez (b) (4)	22 Oct 2020 18:56:42

US3322048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Requery-Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',however, no corresponding data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:53:40
User closed query 'Per CDM-Kindly consider to update response provided in previous query into the data field 'Primary reason for dosing discontinuation'.Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:38:17
Query 'Per CDM-Kindly consider to update response provided in previous query into the data field 'Primary reason for dosing discontinuation'.Thank you.' answered with 'entered, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 14:36:25
User entered 'Due to SARS-COV-2 (COVID)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 14:36:18
User opened query 'Per CDM-Kindly consider to update response provided in previous query into the data field 'Primary reason for dosing discontinuation'.Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:49:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 07:49:11
Query 'Data is required. Please complete.' answered with 'Confirmed COVID 19 case at baseline' (Site from System).	Frances Saubon (b) (4) (b) (4)	12 Oct 2020 16:47:53
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 16:46:10
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	12 Oct 2020 16:46:10
User entered 'Due to SARS-COV-2 (COVID)'	Frances Saubon (b) (4) (b) (4)	12 Oct 2020 16:45:02

US3322048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:01

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Oct 2020 16:45:02